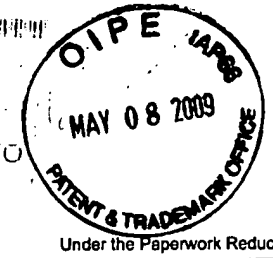
05/08/09

64811 U.S. PTO



Reexam 95000468

64811 U.S PTO

PTO/SB/58 (02-09)
Approved for use through 08/31/2010. OMB 0651-0033
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

(Also referred to as FORM PTO-1465)

REQUEST FOR *INTER PARTES* REEXAMINATION TRANSMITTAL FORM

Address to:
Mail Stop *Inter Partes* Reexam
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Attorney Docket No.: 47063.000072

Date: May 8, 2009

1. ☒ This is a request for *inter partes* reexamination pursuant to 37 CFR 1.913 of patent number 6,623,486 issued September 23, 2003. The request is made by a third party requester, identified herein below.

2. ☒ a. The name and address of the person requesting reexamination is:

Smith & Nephew, Inc.

1450 Brooks Road

Memphis, TN 38116

b. The real party in interest (37 CFR 1.915(b)(8)) is: Smith & Nephew, Inc.

3. ☐ a. A check in the amount of $_____ is enclosed to cover the reexamination fee, 37 CFR 1.20(c)(2);

☒ b. The Director is hereby authorized to charge the fee as set forth in 37 CFR 1.20(c)(2) to Deposit Account No. 50-0206 ; **or**

☐ c. Payment by credit card. Form PTO-2038 is attached.

4. ☐ Any refund should be made by ☐ check or ☐ credit to Deposit Account No. _____ 37 CFR 1.26(c). If payment is made by credit card, refund must be to credit card account.

5. ☒ A copy of the patent to be reexamined having a double column format on one side of a separate paper is enclosed. 37 CFR 1.915(b)(5)

6. ☐ CD-ROM or CD-R in duplicate, Computer Program (Appendix) or large table
☐ Landscape Table on CD

7. ☐ Nucleotide and/or Amino Acid Sequence Submission
If applicable, items a. – c. are required.

a. ☐ Computer Readable Form (CRF)

b. Specification Sequence Listing on:

i. ☐ CD-ROM (2 copies) or CD-R (2 copies); **or**

ii. ☐ paper

c. ☐ Statements verifying identity of above copies

8. ☒ A copy of any disclaimer, certificate of correction or reexamination certificate issued in the patent is included.

9. ☒ Reexamination of claim(s) 1-18 is requested.

10. ☒ A copy of every patent or printed publication relied upon is submitted herewith including a listing thereof on Form PTO/SB/08, PTO-1449, or equivalent.

05/20/2009 RBELL1 00000001 500206 95000468
01 FC:1815 8300.00 DA

11. ☒ An English language translation of all necessary and pertinent non-English language patents and/or printed publications is included.

12. ☒ The attached detailed request includes at least the following items:

a. A statement identifying each substantial new question of patentability based on prior patents and printed publications. 37 CFR 1.915(b)(3)
b. An identification of every claim for which reexamination is requested, and a detailed explanation of the pertinency and manner of applying the cited art to every claim for which reexamination is requested. 37 CFR 1.915(b)(1) & (3).

13. ☒ It is certified that the estoppel provisions of 37 CFR 1.907 do not prohibit this reexamination. 37 CFR 1.915(b)(7)

14. ☒ a. It is certified that a copy of this request has been served in its entirety on the patent owner as provided in 37 CFR 1.33(c).
The name and address of the party served and the date of service are:

Brian Poissant, Jones Day

222 East 41st Street

New York, NY 10017-6702

Date of Service: May 8, 2009 ; **or**

☐ b. A duplicate copy is enclosed because service on patent owner was not possible. An explanation of the efforts made to serve patent owner **is attached.** See MPEP 2620.

15. Third Party Requester Correspondence Address: Direct all communications about the reexamination to:

☒ The address associated with Customer Number: 21967

OR

☐ Firm or Individual Name

Address

City	State	Zip
Country		
Telephone	Email	

16. ☒ The patent is currently the subject of the following concurrent proceeding(s):

☐ a. Copending reissue Application No.

☒ b. Copending reexamination Control No. 90/009,378

☐ c. Copending Interference No.

☒ d. Copending litigation styled:
Synthes (USA) vs. Smith & Nephew, Inc.
Case No.: 03-0084, E.D.P.A.

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

Authorized Signature	May 8, 2009 Date
Robert A. King Typed/Printed Name	42,738 Registration No., if applicable

Privacy Act Statement

The **Privacy Act of 1974 (P.L. 93-579)** requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.*, GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent Number	:	6,623,486
Issued	:	September 23, 2003
Application Number	:	09/660,287
Filing date	:	September 12, 2000
Title	:	BONE PLATING SYSTEM
Docket No.	:	47063.000072
Customer No.	:	**21967**

Attn: Mail Stop "*Inter Partes* Reexamination"
Central Reexamination Unit
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Request for *Inter Partes* Reexamination of U.S. Patent No. 6,623,486

Sir:

Reexamination under 35 U.S.C. §§ 311-318 and 37 C.F.R. §§ 1.903-927 is hereby requested for claims 1-18 of U.S. Patent No. 6,623,486 (the "'486 Patent") (Exhibit A), entitled "Bone Plating System," which is assigned to Synthes USA, LLC ("Synthes") (Reel/Frame 011364/0057 and 022299/0001).

This request is being made by third party Requester Smith & Nephew, Inc., which is also the real party in interest (37 C.F.R. 1.915(b)(8)).

Requester Smith & Nephew requested *ex parte* reexamination of the '486 patent on January 8, 2009 and the request for *ex parte* reexamination was granted on February 14, 2009 (control no. 90/009,378). This *inter partes* request relies entirely upon new prior art, none of which was cited or relied upon by Requester in its January 8, 2009 *ex parte* request, in support of the substantial new questions of patentability described herein. Requester believes that merger of the *ex parte* proceeding would be appropriate in accordance with 37 C.F.R. § 1.989(b).

The Director is hereby authorized to charge the fee as set forth in 37 C.F.R. 1.20(c)(2), to Deposit Account No. 50-0206. It is believed that no other fees are required for consideration of this inter partes reexamination request. However, should any additional fees be necessary, the Commissioner is authorized to charge such fees to Deposit Account No. 50-0206.

A copy of the patent to be reexamined, in double column format and printed on only one side of the page, is enclosed as Exhibit A to this request. A copy of every patent or printed publication relied upon is submitted herewith including a listing thereof on the attached Form PTO/SB/08.

The '486 Patent is currently the subject of the following copending litigation styled: *Synthes (U.S.A.) v. Smith & Nephew, Inc.* (E.D. Pa. Case No. 03-0084).

It is certified that the estoppel provisions of 37 C.F.R. § 1.907 do not prohibit this reexamination. 37 C.F.R. 1.915(b)(7).

A copy of this request and all papers and references filed in support thereof was served by first class mail on May 8, 2009, as provided in 37 C.F.R. 1.33(c), on the patent owner of record by its representative:

Brian M. Poissant, Esquire
Jones Day
222 East 41st Street
New York, NY 10017

Please direct all communications for the third party Requesters to the address associated with Customer No. **21967**.

A statement identifying each substantial new question of patentability based on the references being relied upon, an identification of every claim for which reexamination is

requested, and a detailed explanation of the pertinence and manner of applying each cited reference to every claim for which reexamination is requested, are included in the request below.

TABLE OF CONTENTS

I. THE '486 PATENT AND RELATED LITIGATION

A. SUBJECT MATTER OF THE '486 PATENT

The '486 patent includes system claims directed to bone plating systems, and method claims relating to fracture fixation using a bone plate.

1. System Claims

The '486 patent system claims (claims 1-9 and 14-18) all require certain common elements. Specifically, claims 1, 14, and 16-18, which are the independent claims, all require:

- a head portion to match the metaphysis of a bone;
- a shaft portion to match the diaphysis of a bone;
- a combination of threaded "first" holes and unthreaded "second" holes;[1]
- first screws, for use in the first holes, with threads on the screw head that mate with the threads in the first holes, and threads on the screw shaft; and
- second screws, for use in the second holes, with threads on the shaft.

Claim 1 of the '486 patent is representative:

> A bone plating system for fixation of bone comprising:
> a bone plate having:
> an upper surface; a bone-contacting surface;
> at least one first hole passing through the upper and bone-contacting surfaces and having a thread;
> and at least one second hole passing through the upper and bone-contacting surfaces;
> a first screw having a shaft with a thread for engaging bone and a head with a thread configured and dimensioned to mate with the thread of the first hole;
> and a second screw having a shaft with a thread for engaging bone and a head,
> wherein the first and second screws remain seated in their respective holes for substantially as long as the bone plate is implanted,

[1] In this Request, Smith & Nephew applies the following claim construction adopted by the district court for "second holes": "a hole that is not threaded (*i.e.,* does not have any threads)". While the claim constructions adopted by the district court are not binding on the Patent Office, a copy of the Court's claim construction order from the *Synthes v. Smith & Nephew* case is attached at Exhibit B.

wherein the bone plate includes a plurality of first and second holes, and a corresponding plurality of first and second screws are provided, and

wherein the bone plate includes a head portion configured and dimensioned to conform to a metaphysis of a bone and a shaft portion configured and dimensioned to conform to a diaphysis of a bone and the head portion has only first plate holes.

The remaining independent system claims (claims 14, and 16-18) are all virtually identical to claim 1, and differ only in the recitation of their respective final "wherein" clauses. Specifically:

- Claim 14 requires the head portion of the plate to flare outward from the shaft;
- Claim 16 requires the head portion to have a curved surface and anterior and posterior forks;
- Claim 17 requires the shaft portion of the plate to have both first and second plate holes; and
- Claim 18 requires the shaft to have a trapezoidal shaped cross section in certain regions.

2. **Method Claims**

The '486 patent method claims (claims 10-13) all stem from independent claim 10, which recites:

A method for fracture fixation of bone comprising the steps of:

reducing the fracture to bring bone fragments in close apposition;

compressing a bone plate against the bone with at least one first fastener to hold the fracture reduction; and

securing at least one second fastener at a fixed angular relationship to the bone plate,

wherein the at least one first fastener is inserted before the at least one second fastener and the at least one first fastener and

the at least one second fastener remain in bone for substantially as long as the bone plate is implanted.

The remaining method claims — claims 11-13 — depend from claim 10.

Method claim 10 is written broadly, and should be given its broadest reasonable interpretation for purposes of examination. *See* M.P.E.P. § 2111. For example, while claim 10 requires a "first fastener" to compress the plate to the bone, and a "second fastener" that is at a fixed angular relationship to the bone, it does not require the second fastener to be any particular

kind of locking device (such structural limitations appear only in the system claims). Claim 10 also does not require the "first fastener" to be a particular kind of screw — any fastener (even one that locks to the plate) that compresses the plate to the bone falls within the scope of this term. Furthermore, although claim 10 requires the "first fastener" to be installed before the "second fastener," this does not preclude other fasteners (either "first" or "second") being installed before the claimed method steps begin or after they end. Thus, any surgical procedure that involved installing a screw that compresses and holds the fracture reduction, followed by a locking screw, falls within the scope of claim 10, regardless whether other screws of any kind are installed before or after these two screws.

II. SUMMARY OF PRIOR ART AND PRINTED PUBLICATIONS UPON WHICH THE REEXAMINATION REQUEST IS BASED

A large number of prior art references disclose some or all of the features recited in the '486 patent, and many references provide specific motivations to combine these features to obtain the claimed subject matter. As such, there are multiple substantial new questions of patentability regarding the '486 patent claims. For clarity, Requester has separated the statement of substantial new questions of patentability into a first group addressing the method claims (claims 10-13), and a second group. addressing the apparatus claims (claims 1-9 and 14-18). Some references appear in both sections.

With respect to the **Method Claims** (claims 10-13), Requester relies on the following references that raise substantial new questions of patentability:

- Schuhli Technique Guide, Synthes, 1995 (the "Schuhli Guide");
- Kassab, S.S., *et al.*, "Patients Treated for Nonunion with Plate and Screw Fixation and Adjunctive Locking Nuts," Clin. Ortho. and Related Research, vol. 347, pp. 86-92, Lippencott-Raven Publishers, February 1998 (the "Kassab Article");
- U.S. Pat. No. 5,013,313 ("Surer");
- German Patent No. DE 43 43 117 A1 ("Wolter 117");

- U.S. Pat. No. 5,976,141 ("Haag");
- The Locking Reconstruction Plate Technique Guide, Synthes Maxillofacial, 1997 (the "Recon Plate Guide").

With respect to the **System Claims** (claims 1-9 and 14-18), Requester relies on the following references or combinations of references that raise substantial new questions of patentability:

- WO 99/25266 to Mückter ("Mückter")[2];
- "Summary of Safety and Effectiveness Information" no. K982222 ("K982222"), published August 26, 1998;
- The Schuhli Guide;
- The Kassab Article;
- Periarticular Plating System (Advertisement), J. Ortho. Trauma, vol. 12, no. 5, Lippencott-Raven Publishers, June/July 1998 (the "Zimmer Ad");

Requester also relies on the following additional references as secondary references herein and in the attached claim charts:

- U.S. Pat. No. 5,810,823 ("Klaue '823");
- U.S. Pat. No. 5,190,544 ("Klaue '544);
- U.S. Pat. No. 4,484,570 ("Sutter");
- U.S. Pat. No. 4,537,185 ("Stednitz");
- U.S. Pat. No. 5,129,901 ("Decoste");
- U.S. Pat. No. 5,190,544 ("Chapman");
- U.S. Pat. No. 5,429,641 ("Gotfried");
- U.S. Pat. No. 5,601,553 ("Trebing");
- Admitted Prior Art in U.S. Pat. No. 6,623,486;
- Haas, N.P., et al., entitled "LISS – Less Invasive Stabilization System – A New Internal Fixator for Distal Femur Fractures," OP J., vol. 13(3), pp. 340-344, Georg Thieme Verlag, December 1997 (the "Haas Article");

[2] For simplicity, this request cites to the U.S. version of Mückter — U.S. Patent No. 6,468,278 — which provides a translation of the international application. In any event, the drawings provided in WO 99/25266 fully support Requesters comments herein.

- Synthes 1997 Catalog;
- Bolhofner, B.R., *et al.*, "The Results of Open Reduction and Internal Fixation of Distal Femur Fractures Using a Biologic (Indirect) Reduction Technique," J. Ortho. Trauma, vol. 10, no. 6, pp. 372-377, Lippencott-Raven Publishers, 1996 ("Bolhofner");
- "Instruments de Chirurgie," 1935 ("Collin Catalog"); and
- Müller, M.E., *et al.*, "Manual of Internal Fixation, Techniques Recommended by the A0-ASIF Group," Third Edition, Springer-Verlag 1995 ("Manual of Internal Fixation").

Each of the foregoing references qualifies as prior art to the '486 patent, which was filed on September 12, 2000 and claims priority to a provisional patent application (No. 60/153,239) filed on September 13, 1999. A reference qualifies as prior art under 35 U.S.C. § 102(a) if it was "patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent," which is presumed to be the earliest filing date supporting the particular claim. A reference qualifies as prior art under 35 U.S.C. § 102(b) if it was "patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States," in other words, before September 13, 1998 for claims supported by the disclosure in provisional application No. 60/153,239, and September 12, 1999 for the remaining claims.[3]

[3] Provisional application No. 60/153,239 did not include features such as suture holes (claim 15) and tibia plates (claim 12), which were first added in utility application 09/660,287.

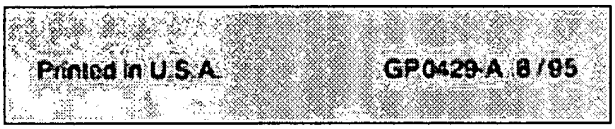
III. STATEMENT OF NEW QUESTIONS OF PATENTABILITY

'486 PATENT METHOD CLAIMS

A. SUBSTANTIAL NEW QUESTIONS OF PATENTABILITY STEMMING FROM THE SCHUHLI GUIDE

1. The Schuhli Guide Is Prior Art

Requester relies on a Synthes' "Schuhli Technique Guide," dated 1995. The Schuhli Guide is a printed publication. For example, the last page of the Schuhli Technique Guide shows a copyright date of 1995, and a revision date of "8/95":



The relevant public to which the Schuhli Technique Guide was disseminated or otherwise made available would be surgeons, as they are the customers to whom bone plates are marketed and sold, and they are also the hypothetical person having ordinary skill in the art for the '486 patent. The Schuhli Technique Guide contains no restrictions on distribution or any other indications that the Schuhli Technique Guide is confidential. Accordingly, the Schuhli Technique Guide was sufficiently accessible to those concerned with the art to constitute a printed publication and is thus prior art to the '486 patent. The Schuhli Technique Guide is not of record in the prosecution history of the '486 patent application.

2. The Schuhli Guide Disclosure

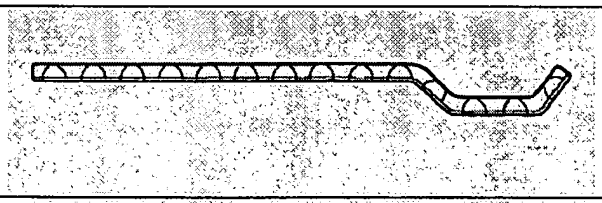
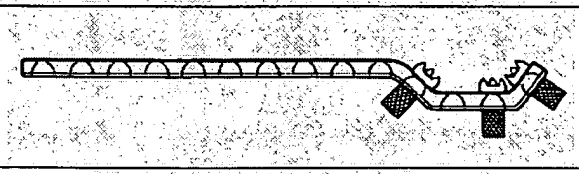
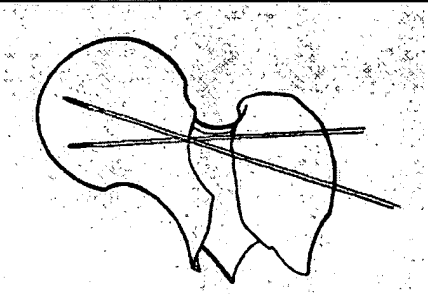
The Schuhli Guide discloses new teachings and raises a substantial new question of patentability not raised during prosecution or in the *Ex parte* Reexamination. The Schuhli Guide discloses the following key surgical method steps:

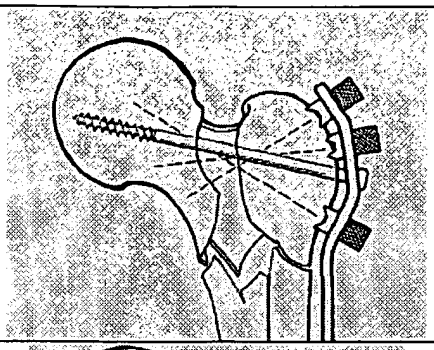
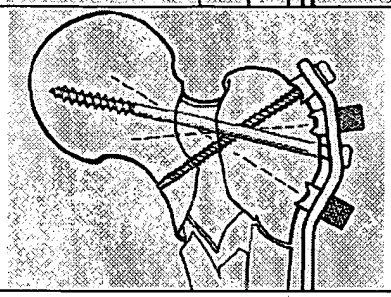
- reducing the fracture to bring the bone fragments into close apposition;
- compressing the plate to the bone to hold a fracture reduction using a first fastener;

- installing a second fastener comprising a threaded screw at a fixed angular relationship to the plate *after* installing the first fastener; and
- leaving the screws in place with the bone plate.

The Schuhli Guide describes a threaded "washer" that fits into the holes through standard Dynamic Compression Plates ("DCP") and Limited Contact Dynamic Compression Plates ("LC-DCP"). *See* Schuhli Guide, inside cover. The Schuhli Washer "fits between the underside of the plate and the bone." *Id.* When the Schuhli Washer engages the screw, it locks the screw to the plate at a 90° angle, "which allows the construct to act as a fixed-angle device." *Id.* The Schuhli Guide discloses several techniques for using the Schuhli Washer, at least two of which describe the steps recited in claim 10: "Special Application — Fracture," *id.* at 5-8, and "Case 3." *Id.* at 15.

The Schuhli Guide describes the first five steps of the "Special Application — Fracture" method as follows:

(1) fit the plate to the bone;	
(2) assemble the Schuhli Washers in the plate;	
(3) reduce and stabilize the fracture;	

(4) insert cancellous bone screw;	
(5) insert cortex screws through Schuhli Washers	

Id. at 6-7. The Schuhli Guide cover illustration shows a similar procedure, but using a LC-DCP plate having arched cutouts along the lower surface. *Id.*, cover.

While the above figures from the Schuhli Guide illustrate the bone plate standing slightly off the surface of the bone, the Schuhli Guide itself makes no distinction between the plate contacting the bone directly versus contacting the bone *via* the Schuhli Washers. In fact, with regard to the surgical technique, "Special Application — Osteotomy,"[4] which is virtually identical to the "Special Application — Fracture" method, the Schuhli Guide states that the first screw "presses the plate along the contoured upper end into the trochanter." *Id.* at 10. Similarly, in "Case 2," the Schuhli Guide describes a procedure in which a 6.5 mm screw is used "to anchor the plate through the trochanter." *Id.* at 14. Thus, the Schuhli Guide itself equates contact via the Schuhli Washers with pressing the plate against the bone.

[4] This application is very similar to "Special Application — Fracture," but describes an "osteotomy" procedure in which the bone is deliberately severed and realigned to correct a deformation.

The Schuhli Guide also discloses a surgical procedure referred to as "Case 3," in which Schuhli Washers were used in conjunction with conventional screws to address a persistent nonunion of the humerus. *Id* at 15. In Case 3, a 14-hole reconstruction plate was contoured into a "wave" and placed on the bone across the nonunion (*i.e.,* the fracture). The Schuhli Guide explains that "[t]he plate was anchored to the bone proximally and distally," *id.*, meaning it was secured to the bone on each side of the fracture, which would necessarily help hold the fracture reduction. Next, "[t]wo screws were inserted at the level of the nonunion and locked to the plate with Schuhlis, providing a bridge construct of great stability in the area of the nonunion." *Id.* Thus, Case 3 describes installing first fasteners to secure the plate to the bone, and second fasteners, after the first fasteners, at a fixed angle to the plate. An X-ray from a similar surgery is shown in the right-hand illustration on the Schuhli Guide cover. *Id.*, cover.

Both of the foregoing surgical techniques disclose each and every element of claim 10. The subject matter of claims 11-13 is also found in the Schuhli Guide. For example, the fracture in the "Special Application — Fracture" method is a peri-articular fracture (claim 11) of the proximal femur (claim 12), and includes a third fixed-angle fastener at a different angle than the second fastener (claim 13). *Id.* at 8.

3. The Schuhli Guide Raises A Substantial New Question of Patentability

The Schuhli Guide raises new, non-cumulative technological teachings that were not previously considered and discussed on the record during prosecution of the '486 patent or in the *Ex parte* Reexamination. Claim 10 (pending as application claim 18) was rejected solely over Soviet Union Patent SU 1279-626-A1 ("Traumatology Orthop"), and was overcome because Traumatology Orthop was argued not to disclose the recited step of installing "the at least one first fastener ... before the at least one second fastener." The Schuhli Guide raises substantial

new questions over those presented by Traumatology Orthop. For example, unlike Traumatology Orthop, the Schuhli Guide:

- specifically describes and illustrates, in a technique guide format, the claimed reduction step;
- specifically describes and illustrates, in a technique guide format, installing the first fastener to compress the plate to the bone;
- specifically describes and illustrates, in a technique guide format, installing a second fastener at a fixed angle to the plate, after installing the first fastener; and
- specifically describes and illustrates, in a technique guide format, leaving the screws in place after the operation.

In contrast, Traumatology Orthop only shows the fasteners in place in the plate, fails to discuss or illustrate the surgical steps, and fails to disclose the claimed order of fixation. The question of patentability raised by the Schuhli Guide is substantially different from the question raised in the previous examination of the '486 patent. *See* 35 U.S.C. § 312; *and* M.P.E.P. § 2616.

Similarly, the Schuhli Guide includes new, non-cumulative technological teachings that are not present in the prior art cited in the *Ex parte* Reexamination. The first reference cited in the *Ex parte* Reexamination is The Titanium Distal Radius Plate Technique Guide, published by Synthes, 1997 (the "DRP Guide"). The Schuhli Guide differs from the DRP Guide in several important respects. For example, the Schuhli Guide:

- describes a threaded screw as the second, fixed-angle fastener (the DRP Guide discloses a threaded-head locking *pin*)[5];

[5] In the co-pending litigation between Requester and Synthes, Requester Smith & Nephew filed a motion of summary judgment that claims 10-12 were invalid over the DRP Guide. In opposition to Smith & Nephew's motion, Synthes argued that the DRP Guide pins are not "fasteners" as required by claim 10. While Requester disagrees with Synthes Position, the fact that the Schuhli Guide discloses a screw rather than the locking pin disclosed in the DRP Guide demonstrates that the Schuhli Guide's disclosure is particularly relevant to the Substantial New Question analysis.

- illustrates the fracture reduction step (the DRP Guide indicates that a fracture is reduced, but does not illustrate the step);
- specifically describes and illustrates installing the first fastener to compress the plate to the bone and hold the reduction, and then installing the second fastener at a fixed angle to the plate (the DRP Guide discloses, but does not illustrate, the claimed order); and
- describes the method being used to secure a proximal femur fracture, as recited in claim 12 (the DRP Guide does not disclose the bones listed in claim 12).

The next reference relied on in the *Ex parte* Reexamination is Koval, K., *et al.*, "Distal Femoral Fixation: A Biomechanical Comparison of the Standard Condylar Buttress Plate, a Locked Buttress Plate, and the 95-Degree Blade Plate," J. of Orthopaedic Trauma, vol. 11(7), pp. 521-524, Lippencott-Raven Publishers, October 1997 (the "Koval Article"). The Schuhli Guide differs from the Koval Article in several key respects. For example, the Schuhli Guide:

- specifically describes and illustrates, in a technique guide format, reducing a bone fracture from several disparate fragments into a structured bone shape (the Koval Article does not illustrate reducing the bone fracture);
- specifically illustrates, in a technique guide format, installing the first fastener to compress the plate to the bone (the Koval Article does not illustrate installing the first fasteners);
- specifically describes and illustrates, in a technique guide format, installing a second fastener at a fixed angle to the plate, after installing the first fastener (the Koval Article discloses the order of fixation as being one of only two possible orders, but does not expressly describe the order); and
- specifically describes and illustrates, in a technique guide format, leaving the screws in place after the operation (the Koval Article describes a laboratory study, not a surgical procedure).

Finally, the *Ex parte* Reexamination relied on Haas, N.P., *et al.*, "LISS – Less Invasive Stabilization System – A New Internal Fixator for Distal Femur Fractures," OP J., vol. 13(3), pp. 340-344, Georg Thieme Verlag, December 1997 (the "Haas Article"). The Schuhli Guide also differs from the Haas Article in several key respects. For example, the Schuhli Guide:

- specifically describes and illustrates, in a technique guide format, the steps of reducing and securing a bone fracture using compression screws and fixed-angle screws (the Haas Article does not illustrate the surgical steps); and

- illustrates and describes a bone plate having a mix of compression screws and fixed-angle screws being used in the same plate to secure a bone fracture (the Haas Article does not disclose any screws other than fixed-angle screws).

As explained above, the Schuhli Guide discloses a number of new, non-cumulative technological teachings that are relevant to patentability but that not are found in the prior art considered during original examination or in the *Ex parte* Reexamination. Therefore, the Schuhli Guide raises a question of patentability that is substantially different from the questions previously raised. *See* 35 U.S.C. § 312; *and* M.P.E.P. § 2616.

A substantial new question of patentability as to claims 10-13 is therefore raised by the Schuhli Guide.

B. SUBSTANTIAL NEW QUESTIONS OF PATENTABILITY STEMMING FROM KASSAB

1. The Kassab Article Is Prior Art

In February of 1998 inventors Jeff Mast and Keith Mayo, along with lead author Safa Kassab, published an article in Clinical Orthopaedics and Related Research (vol. no. 347) entitled "Patients Treated for Nonunion with Plate and Screw Fixation and Adjunctive Locking Nuts" (the "Kassab Article"). The Kassab Article qualifies as prior art to the '486 patent under 35 U.S.C. § 102(b). The Kassab Article was not of record in the prosecution history of the '486 patent application.

2. The Kassab Article Disclosure

The Kassab Article provides a substantial new question of patentability not raised during prosecution or in the *Ex parte* Reexamination. In particular, the Kassab Article discloses:

- placing a plate on a bone;
- "tensioning" the plate (i.e., installing it with screws) to hold the fracture reduction;
- installing a locking screw after tensioning the plate; and
- leaving the screws in place with the plate.

The Kassab Article describes a number of surgical procedures in which a locking nuts (in particular, Schuhli nuts) are used on the underside of a bone plate "to lock a 4.5-mm bone screw to the Dynamic Compression Plate (DCP), (Synthes USA) independent of bony contact with the plate." Kassab at 86. The Kassab Article describes three primary uses for locking nuts: when the bone structure was compromised due to bone loss or a previously-removed screw, where there are high mechanical loads, and in severely osteoporotic bone. *Id.* at 87. The Kassab Article further noted that locking nuts like the Schuhli nut can be used "to create a fixed angle relationship at any screw hole." *Id* at 91.

In one procedure, described with reference to Figures 3A-D, the surgeon removed a dynamic screw plate (shown implanted in Fig. 3A) and replaced it with a 95 degree blade plate. *See id.*, Figs. 3B-D and description thereof. The Kassab Article explains that the 95 degree blade plate is installed and "after tensioning," a Schuhli nut is used "at distal screw Number 4 on the proximal side of the osteotomy." *Id.* As shown in Figures 3B-D, the Schuhli nut is located along the plate shaft. In order to explain the meaning of the Kassab Article, the Requester relies on the Manual of Internal Fixation, which describes "tensioning" a plate to the bone in several contexts. In a first context, the plate is secured to the bone on one side of the fracture by a screw and then a "tensioning device" is used to pull the plate along the bone to compress the fracture before the remaining screws are installed. *See* Manual of Internal Fixation at 218-223. In another context, the plate is described as being applied using "tension band fixation," in which the plate is secured with screws to the side of the bone that experiences tension (as opposed to compression). *Id.* at 226-227. In either event, the plate is secured to the bone using conventional non-locking screws in order to mount the plate in tension on the bone and thereby compress the fracture together.

The Kassab Article discloses every element of claim 10. As explained above, the procedure in Figures 3A-D involved installing a 95 degree blade plate on the bone and "tensioning" it — meaning that the plate was secured to the bone by first fasteners to hold the fracture reduction. *See* Kassab at 91. After tensioning, a screw was installed through a Schuhli nut, which locked that screw at a fixed angle with respect to the bone plate. *Id.* As can be seen in the x-rays, the fasteners all remained in place with the plate after the surgery. *Id.*

3. Kassab Raises Substantial New Questions of Patentability

The Kassab Article raises new, non-cumulative technological teachings that were not previously considered and discussed on the record during prosecution of the '486 patent or in the *Ex parte* Reexamination. As explained above, "Traumatology Orthop" was applied during prosecution. Unlike Traumatology Orthop, the Kassab Article:

- specifically describes the order of installing the plate to the bone using screws and then installing a "second fastener" at a fixed angular relationship to the bone plate; and
- specifically describes the bone screws being left in place after the operation.

Traumatology Orthop fails to disclose the claimed order, and fails to specifically describe or show the screws being left in place after the surgery. As such, the question of patentability raised by the Kassab Article is substantially different from the question raised in the previous examination of the '486 patent. *See* 35 U.S.C. § 312; *and* M.P.E.P. § 2616.

Similarly, the Kassab Article includes new, non-cumulative technological teachings that are not present in the prior art cited in the *Ex parte* Reexamination. In particular, unlike the DRP Guide, the Kassab Article:

- describes a threaded screw as the "second fastener" (the DRP Guide discloses a threaded-head locking pin);

- describes installing a blade plate and "tensioning" it — which is understood to include the steps of reducing the fracture and holding the plate to the bone using first fasteners that hold the fracture reduction) — and then installing the second fastener at a fixed angular relation to the plate (the DRP Guide discloses, but does not illustrate, the claimed order); and
- describes the method being used to secure a distal femur fracture, as recited in claim 12 (the DRP Guide does not disclose the bones listed in claim 12).

The Kassab Article is also substantially different from the Koval Article. For example, the Kassab Article:

- describes installing a blade plate and "tensioning" it — which is understood to include the steps of reducing the fracture and holding the plate to the bone using first fasteners that hold the fracture reduction) — and then installing the second fastener at a fixed angular relation to the plate (the Koval Article discloses the order of fixation as being one of only two possible orders, but does not expressly describe the order); and
- specifically describes and illustrates the first and second fasteners remaining in place with the bone plate after surgery (the Koval Article describes a laboratory study, not a surgical procedure).

Finally, Kassab Article differs from the Haas Article in several key respects. For example, the Kassab Article:

- describes installing a blade plate and "tensioning" it — which is understood to include the steps of reducing the fracture and holding the plate to the bone using first fasteners that hold the fracture reduction) — and then installing the second fastener at a fixed angular relation to the plate (the Haas Article does not illustrate the surgical steps); and
- illustrates and describes a bone plate having a mix of compression screws and fixed-angle screws being used in the same plate to secure a bone fracture (the Haas Article does not disclose any screws other than fixed-angle screws).

In view of at least the foregoing key differences between the Kassab Article and the previously-considered references, the question of patentability raised by the Kassab Article is substantially different from the questions raised during original prosecution and in the *Ex parte* Reexamination. *See* 35 U.S.C. § 312; *and* M.P.E.P. § 2616.

A substantial new question of patentability as to claims 10-13 is therefore raised by the Kassab Article.

C. SUBSTANTIAL NEW QUESTIONS OF PATENTABILITY STEMMING FROM SURER

1. Surer Is Prior Art

U.S. Patent 5,013,313 to Surer ("Surer") issued on May 7, 1991, making it prior art under 35 U.S.C. § 102(b). Surer is not of record in the prosecution history of the '486 patent application.

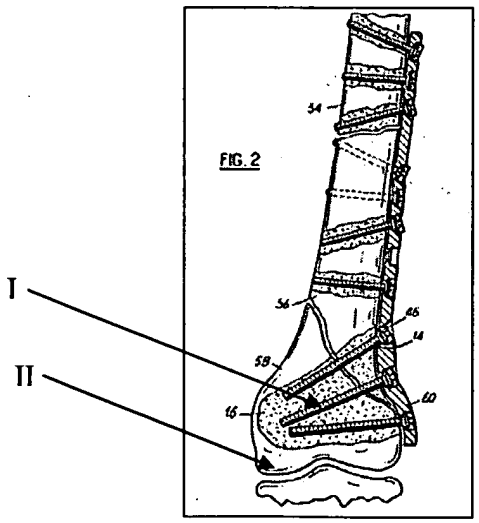
2. The Surer Disclosure

Surer raises a substantial new question of patentability not raised during prosecution or in the *Ex parte* Reexamination ordered on February 14, 2009. In particular, Surer discloses a surgical device and method in which a plate is secured by multiple fasteners that *each* compress the plate to the bone to hold the fracture reduction *and* are locked at a fixed angle to the plate.

As shown in Figure 2 and described in the Abstract, Surer discloses a device and method "for the fixation of implants or ancillary material on bones." *See* Surer, Abstract. In particular, Surer discloses holding fractured bone fragments ("fragments 56 and 58") in close apposition using a plate ("part 10"/"plate 60"). *Id.*, at col. 4, ll. 13-18. This necessarily requires the step of reducing the fracture to bring the fragments into close apposition,[6] because otherwise the fracture would heal improperly or would not heal at all. Surer also discloses compressing the bone plate (60) against the bone (identified as "support 12") with screw 14. *Id.*, at col. 3, ll. 43-45 ("Such a device is put into position in the following manner: the screw 14 is screwed into the support 12

[6] As will be appreciated, bone fragments are displaced by skeletal trauma, and tension in the connective tissue and tendons tends to pull the fragments and hold them out of alignment. Thus, a key initial step in any osteosynthesis procedure is to "reduce" the fragments to bring them into their original orientation. In fact, the bone shown in Figure 2 of Surer could not be secured as shown without first reducing the fracture.

to the desired depth, for example until the part 10 comes into contact with the support, but nevertheless without exerting a noticeable pressure on this support."); *see also, id.* at col. 4, ll. 24-27 (explaining that the "support" is the bone). While Surer states that screw 14 is secured "without exerting a noticeable pressure on this support," it clearly does exert enough pressure to compress the plate to the bone and to hold the fracture reduction, and satisfies the corresponding claim element.[7] In fact, the screws shown in Surer can — and do, at least to some degree — operate as conventional compression screws that hold the plate to the bone. Surer explains that "screws 14" is secured at a fixed angular relationship to the bone plate by installing a "locking screw 49" over the end of "screw 14," but this does not negate the compression provided by installing the "screw 14" in the first place. *Id.* at col. 3, ll. 49-53 ("The locking screw 49 is screwed into the countersink 36 . . . consequently ensuring the fixation of the screw 14 relative to the part 10."); *and* col. 4, ll. 42-43 ("the screws themselves are immobilized relative to the plate"). For convenience, Surer Fig. 2 is reproduced below (with annotations):



[7] Claim 10 does not require any minimum amount of compression, and therefore any amount of compression that "compress[es] a bone plate against the bone" satisfies the broadest reasonable interpretation of claim 10.

The entire method of claim 10 is found in Surer. For example, the method of claim 10 is practiced by installing the two screws shown crossing the peri-articular fracture shown in Figure 2, and marked as screws "I" and "II". The "first fastener" — screw "I" — is installed by screwing it into the plate until the plate comes into contact with the bone. *Id.* at col. 3, ll. 43-45. At this point, the threads of the screw are "compressing the bone plate against the bone ... to hold the fracture reduction."[8] Next, the "second fastener" — screw "II" — is installed and secured by its "locking screw 49" to hold it at a fixed angle to the plate. *Id.* at col. 3, ll. 49-53. As explained above, claim 10 does not require the first fastener to not be fixed to the plate, and so the fact that the first fastener might, itself, be secured using its own "locking screw 49" does not take Surer outside the scope of claim 10. Surer also discloses other claimed features, such as a peri-articular fracture (claim 11), a distal femur fracture (claim 12), and securing a third fastener (such as the lowermost screw in Figure 2) at a different fixed angular relationship to the plate than the second fastener (claim 13).

3. Surer Raises a Substantial New Question of Patentability

Surer raises new, non-cumulative technological teachings that were not previously considered and discussed on the record during prosecution of the '486 patent or in the *Ex parte* Reexamination. As noted above, the only art applied during examination — "Traumatology Orthop" — was determined not to disclose the order of fixation. In contrast, Surer:

- describes the installation of a first fastener to compress the plate to the bone and hold the fracture reduction;

[8] While Surer states that the "part" (*i.e.*, the plate) does not exert a noticeable pressure on the "support" (*i.e.*, the bone), *id.* at col. 3, ll. 42-48, the threads of the screw do engage the bone matter to compress the plate against the bone and must hold the fracture reduction.

- describes the installation of a second fastener, after the first fastener, that is secured at a fixed angular relationship to the bone plate; and
- necessarily discloses the order of fixation — regardless of which fastener is installed first — by disclosing two of the Surer screws being installed to secure two bone fragments together.

In fact, the claimed process is followed each time the Surer plate is secured by one screw that holds the fracture reduction and then another screw that is angularly locked. In contrast, Traumatology Orthop does not describe the installation of the screws or compression of the plate to the bone, or the recited order of fixation. Surer includes the very feature deemed lacking in the prior art of record, as well as the remaining claim features, and presents a new question of patentability that is substantially different from the question raised in the previous examination of the '486 patent. *See* 35 U.S.C. § 312; *and* M.P.E.P. § 2616.

Surer also includes new, non-cumulative technological teachings that are not present in the prior art cited in the *Ex parte* Reexamination. Surer discloses the following, not found in the DRP Guide:

- a threaded screw as the "second fastener" (the DRP Guide discloses a threaded-head locking pin);
- a two-part screw system having a screw ("screw 14") that compresses and holds the fracture reduction, and a locking cap ("locking screw 46") that holds the screw at a fixed angle to the plate;
- necessarily discloses the order of fixation — regardless of which fastener is installed first — by disclosing two of the Surer screws being installed to secure two bone fragments together (the DRP Guide discloses the claimed order only when a locking pin is secured after another type of screw); and
- describes and illustrates the use of the claimed method on a distal femur fracture (the DRP Guide does not disclose the method being used on the types of bone described in claim 12).

Surer also discloses the following steps, not found in the Koval Article:

- a two-part screw system having a screw ("screw 14") that compresses and holds the fracture reduction, and a locking cap ("locking screw 46") that holds the screw at a fixed angle to the plate;

- necessarily discloses the order of fixation — regardless of which fastener is installed first — by disclosing two of the Surer screws being installed to secure two bone fragments together (the Koval Article discloses the claimed order only when a second screw is installed through a threaded hole after a first screw is installed through an unthreaded hole); and
- describes and illustrates the first and second fasteners remaining in place with the bone plate after surgery (the Koval Article describes a laboratory study, not a surgical procedure).

Finally, Surer discloses the following steps, not found in the Haas Article:

- a two-part screw system having a screw ("screw 14") that compresses and holds the fracture reduction, and a locking cap ("locking screw 46") that holds the screw at a fixed angle to the plate (the Haas Article discloses only threaded-head locking screws); and
- necessarily discloses the order of fixation — regardless of which fastener is installed first — by disclosing two of the Surer screws being installed to secure two bone fragments together (the Haas Article does not describe the order of fixation).

In view of at least the foregoing key differences between Surer and the previously-considered references, Surer raises substantially different and new questions of patentability over the references applied during original prosecution and in the *Ex parte* Reexamination. *See* 35 U.S.C. § 312; *and* M.P.E.P. § 2616.

A substantial new question of patentability as to claims 10-13 is therefore raised by Surer.

D. SUBSTANTIAL NEW QUESTIONS OF PATENTABILITY STEMMING FROM WOLTER 117

1. Wolter 117 Is Prior Art

German Patent No. DE 43 43 117 A1 to Wolter 117 ("Wolter 117") was laid-open to the public on June 22, 1995. It is therefore prior art under 35 U.S.C. § 102(b). Wolter 117 was cited to the Patent Office in an information disclosure statement dated February 16, 2001 (paper no. 4), but was not discussed on the record or applied against the '486 patent claims during

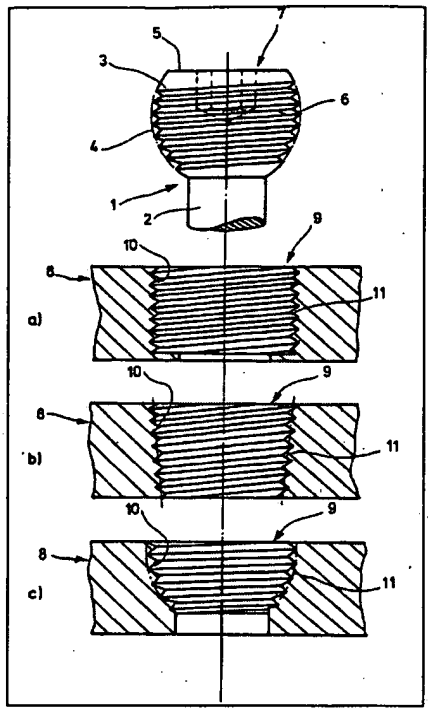
prosecution. Wolter 117 was published in German, and therefore Requester has provided a certified translation with this request.

2. The Wolter 117 Disclosure

Wolter 117 raises a substantial new question of patentability not raised during prosecution or in the *Ex parte* Reexamination. As explained below, Wolter 117 discloses the following key teachings:

- reducing a bone fracture;
- laying the bone plate onto the reduced fracture;
- securing a fastener to compress the plate against the bone surface; and
- securing a fastener at a fixed angular relationship to the bone plate.

Wolter 117 discloses a screw having a threaded head for use in threaded holes in bone plates. *See, e.g.,* Wolter 117, Abstract ("the invention relates to a fixation system for bones which comprises a bone plate"). The screw in Wolter 117 has a spherical threaded head that fits into a cylindrical, conically tapered, or spherical threaded hole. *Id.*, at col. 3, last paragraph ("a bone screw 1 carries on a shaft 2 a screw head 3, which on its lower side comprises an essentially spherical seating face 4. . . . In the seating face 4 an outer thread 6 is preformed."); *see also,* Fig. 1. Installing the threaded-head screw into the threaded hole locks them together to provide "an angularly stable alignment of the plate and screw." *Id.*, col. 1, sixth paragraph. The threads on the screw and in the hole can have a "multiply threaded thread," *id.* at col. 3, second paragraph, such as a dually threaded, interrupted thread. *Id.* (describing Fig. 4). Furthermore, the pitches of the thread on the screw head "can be slightly less than the pitch of the bone thread of the screw in order to achieve a force of compression of the plate against the bone surface. *Id.* at col. 2, second paragraph. Figure 1, which illustrates the threaded head screw and three variants of threaded holes, is reproduced below.



Wolter 117 describes his screw and plate system being a "fixation system for bones." *Id* at col. 1, first paragraph. In this context, Wolter 117 states that typical prior art procedures would involve reducing the fracture and compressing the plate to the bone to hold the fracture reduction:

> ... in the case of a simple tibia fracture, the two bone pieces must be connected to one another, then the metallic bone plate is laid onto the bone pieces to be set. Thereafter, the screws are screwed into the bones so that the seating faces of the screw heads and of the plate holes come to abut one another and the plate is pressed against the bone. A firm connection of bone parts, bone plate, and screws results.

Id. at col. 1, second paragraph. Wolter 117 goes on to state that the "objective of [Wolter 117's] invention is to provide a fixation system of the type stated in the introduction with a selectable and fixable angle between the bone plate and the bone screw." *Id.* at col. 1, seventh paragraph.

Wolter 117 teaches the entire method of claim 10. As explained above Wolter 117 states that the first step in securing a tibia fracture is that "the two bone pieces must be connected to

one another." *Id.* at col. 1, second paragraph. Thus, Wolter 117 discloses the claimed "reducing the fracture" step. Wolter 117 also teaches that the pitch of threads on the screw head can be slightly less than the shaft threads to "achieve a force of compression of the plate against the bone surface." *Id.*, col. 2, second paragraph. Thus, when the surgeon installs the screw, it will press the plate to the bone and hold the previously reduced fracture. The next screw that the surgeon installs will, by virtue of the interlocking threads on the screw head and the plate, be locked at "an angularly stable alignment of the plate and screw." *Id.*, col. 1, sixth paragraph. As with Surer (discussed above) claim 10 does not prohibit the "first fastener" from also locking at a fixed angular relationship to the plate. Nor does claim 10 prohibit the "second fastener" from also compressing the plate to the bone and holding the fracture reduction. As such, any instance in which two of Wolter 117's screws are installed will necessarily result in the claimed method of fixation.

Wolter 117 also discloses the subject matter of claims 11-13. For example, Wolter 117 specifically contemplates a tibia fracture (claim 12), which would obviously include pert-articular fractures (claim 11). In addition, Wolter 117 contemplates that the fasteners can be at different angles from one another (claim 13). *Id.* at col. 1, last paragraph.

3. Wolter 117 Raises A Substantial New Question of Patentability

Wolter 117 raises new, non-cumulative technological teachings that were not previously considered and discussed on the record during prosecution of the '486 patent or in the *Ex parte* Reexamination. As noted above, the prior art applied during prosecution (Traumatology Orthop) failed to disclose installing "the at least one first fastener ... before the at least one second fastener." Wolter 117, on the other hand, does disclose all of the features of claim 10, and necessarily includes the method steps and their order of performance. In fact, unlike Traumatology Orthop, Wolter 117:

- describes the reduction of a bone fracture;
- describes installing a first fastener to compress the plate to the bone, and installing a second fastener, after the first fastener, that is secured at a fixed angular relationship to the bone plate.

Thus, Wolter 117 includes the very feature deemed lacking in the prior art of record, as well as the remaining claim features, and presents a new question of patentability that is substantially different from the question raised in the previous examination of the '486 patent. *See* 35 U.S.C. § 312; *and* M.P.E.P. § 2616.

Wolter 117 also includes new, non-cumulative technological teachings that are not present in the prior art cited in the *Ex parte* Reexamination. For example, unlike the DRP Guide, Wolter 117:

- describes a threaded screw as the "second fastener" (the DRP Guide discloses a threaded-head locking pin);
- describes a bone plate fastener having a threaded shaft and a threaded head that compresses the plate to the bone and secures the screw at a fixed angular relationship to the bone plate;
- necessarily discloses the order of fixation whenever two of the Wolter 117 screws are used to secure bone fragments to a plate (the DRP Guide discloses the claimed order only when a locking pin is secured after another type of screw); and
- describes the foregoing features in the context of a tibia fracture (the DRP Guide does not disclose the method being used on the types of bone described in claim 12).

In addition, in contrast to the Koval Article, Wolter 117:

- describes a "second fastener" that is locked at a fixed angle to the plate and includes a separate threaded head;
- describes a bone plate hole that is formed as part of the plate, instead of being formed in a nut that is welded to the plate;
- describes a single kind of bone plate fastener that compresses the plate to the bone and secures the screw at a fixed angular relationship to the bone plate;
- necessarily discloses the order of fixation whenever two of the Wolter 117 screws are used to secure bone fragments to a plate (the Koval Article discloses the claimed order only when a second screw is installed through a threaded hole after a first screw is installed through an unthreaded hole); and

Finally, unlike the Haas Article, Wolter 117:

- describes the reduction of a tibia fracture (the Haas Article does not disclose this surgical step);
- describes a single kind of bone plate fastener that compresses the plate to the bone and secures the screw at a fixed angular relationship to the bone plate (the Haas Article does not describe its threaded-head screws as being able to compress the plate to the bone);
- necessarily discloses the order of fixation, regardless of which fastener is installed first (the Haas Article does not describe the order of fixation or the compression step).

In view of at least the foregoing distinctions, Wolter 117 raises a substantially new question of patentability over the references raised in the previous examination of the '486 patent and the *Ex parte* Reexamination. *See* 35 U.S.C. § 312; *and* M.P.E.P. § 2616.

A substantial new question of patentability as to claims 10-13 is therefore raised by Wolter 117.

E. SUBSTANTIAL NEW QUESTIONS OF PATENTABILITY STEMMING FROM HAAG

1. Haag is Prior Art

U.S. Patent No. 5,976,141 ("Haag") was filed February 23, 1995 making it prior art under 35 U.S.C. § 102(b). Haag and its us counterpart, International Patent Publication No. WO 96/25892 to Haag *et al.*, published on August 29, 1996, are assigned to Synthes. Neither the U.S. Patent nor the WO publication were not of record during prosecution of the '486 patent application.

2. The Haag Disclosure

Haag raises a substantial new question of patentability not raised during prosecution or in the *Ex parte* Reexamination Request. Haag discloses the following key surgical method steps:

- installing a plate to a bone; and
- installing a second fastener comprising a threaded screw at a fixed angular relationship to the plate *after* installing the plate to the bone.

Haag discloses an insert that is installed into a bone plate hole from above and provides "a means for locking a bone screw to a bone plate at a fixed angle." Haag, col. 2, lines 11-13. Figure 3 of Haag, reproduced below, illustrates the locking insert just before it is pressed into the plate hole:

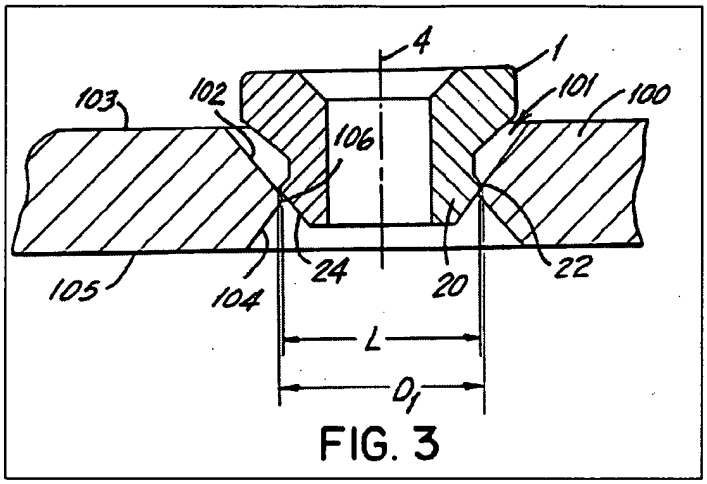


FIG. 3

When a screw is installed into the insert, the screw threads lock with threads in the insert to "prevent[] toggling by holding the screw at a fixed angle with respect to the plate." Col. 3, lines 38-39. Notably, Haag states that the "insert can be pressed into a plate hole in the bone plate before or *after* the plate is installed on the bone." Col. 2, lines 59-60 (emphasis added). This gives the surgeon the option to decide where the inserts — and, consequently, the corresponding fixed-angle locking screws — will be installed, *after* the bone plate is already secured to the bone:

> The insert can be pressed into a plate hole in the bone plate either before or after the plate is installed on the bone.

Id. Haag further states that the plate can be installed with both standard screws and screws through inserts:

> Inserts according to the invention can be installed individually at selected positions on a bone plate, while using standard bone screws without inserts at other locations. Because the inserts are installed in the bone plate from the side opposite the bone, it is possible to install the inserts after the bone plate has been placed on the bone. It is therefore possible to postpone deciding where to use the inserts until after the bone plate is in place, during the operation.

Col. 3, lines 22-29.

While Haag does not specifically discuss the steps of reducing the fracture and compressing the plate to the bone with the first fastener, such steps would be required in an osteosynthesis procedure and therefore are inherent in Haag. As such, Haag discloses all of the limitations of at least claim 10. Additionally, Haag discloses the use of its inserts in buttress plates, which are known to be used in peri-articular regions such as the femur (claims 11 and 12). Col. 3, lines 15-16. It also is inherent in Haag to use a third fastener at an angle different from the second because Haag discusses using multiple inserts on a plate, and shows inserts that fix the screws at different angles Col. 3, lines 9-11; Figs. 7-8 (inserts for use at other angles).

3. Haag Raises Substantial New Questions of Patentability

Haag raises new, non-cumulative technological teachings that were not previously considered and discussed on the record during prosecution of the '486 patent or in the *Ex parte* Reexamination. During prosecution, the sole reference applied against what became claim 10 (Traumatology Orthop) failed to disclose the recited step of installing "the at least one first fastener ... before the at least one second fastener." In contrast to Traumatology Orthop, Haag:

- teaches a threaded insert that can be used at any location on a bone plate to secure a screw to the plate at a fixed angle; and
- teaches the claimed order by instructing that the plate can be "installed on the bone" (necessarily requiring the use of a "first fastener"), ***after which*** the inserts are installed with their corresponding fixed-angle locking screws.

Thus, the question of patentability raised by Haag is substantially different from the question raised in the previous examination of the '486 patent. *See* 35 U.S.C. § 312; *and* M.P.E.P. § 2616.

Similarly, Haag includes new, non-cumulative technological teachings that are not present in the prior art cited in the *Ex parte* Reexamination. In distinction to the DRP Guide, Haag:

- describes a threaded *screw* as the second, fixed-angle fastener (the DRP Guide discloses a threaded-head locking pin);
- teaches a threaded insert that can be used at any location on a bone plate to secure a screw to the plate at a fixed angle; and
- teaches the claimed order by instructing that the plate can be "installed on the bone" (necessarily requiring the use of a "first fastener"), ***after which*** the inserts are installed with their corresponding fixed-angle locking screws.

In contrast to the Koval Article, Haag:

- teaches a threaded insert that can be used at any location on a bone plate to secure a screw to the plate at a fixed angle; and
- teaches the claimed order by instructing that the plate can be "installed on the bone" (necessarily requiring the use of a "first fastener"), ***after which*** the inserts are installed with their corresponding fixed-angle locking screws (the Koval Article discloses the order of fixation as being one of only two possible orders, but does not expressly describe the order).

Finally, in contrast to the Haas Article, Haag:

- expressly teaches the use of non-fixed angle compression screws and fixed-angle screws in the same bone plate (the Haas Article does not discuss non-fixed angle screws being used in the shown plate);
- teaches a threaded insert that can be used at any location on a bone plate to secure a screw to the plate at a fixed angle; and
- teaches the claimed order by instructing that the plate can be "installed on the bone" (necessarily requiring the use of a "first fastener"), ***after which*** the inserts are installed with their corresponding fixed-angle locking screws (the Koval Article discloses the order of fixation as being one of only two possible orders, but does not expressly describe the order).

As explained above, Haag discloses a number of new, non-cumulative technological teachings that are relevant to patentability but that are relevant to patentability but that are not found in the prior art considered during original examination or in the *Ex parte* Reexamination. Therefore, Haag raises a question of patentability that is substantially different from the questions previously raised. *See* 35 U.S.C. § 312; *and* M.P.E.P. § 2616.

Accordingly, Haag raises a substantial new question of patentability of claims 10-13 of the '486 patent.

F. SUBSTANTIAL NEW QUESTIONS OF PATENTABILITY STEMMING FROM THE RECON PLATE GUIDE

1. The Recon Plate Guide is Prior Art

Requester relies on Synthes' publication entitled "The Locking Reconstruction Plate Technique Guide" (the "Recon Plate Guide"), which is dated 1997. The Recon Plate Guide describes techniques for bone reconstruction using Synthes' Mandibular Modular Fixation System. The last page of the Recon Plate Guide shows a copyright date of 1997 and a revision date of "2/97," indicating that the Catalog was printed in February 1997:

© SYNTHES Maxillofacial 1997	GP0556A 2/97

The relevant public to which the Recon Plate Guide was disseminated or otherwise made available would be surgeons, as they are the customers to whom bone plates are marketed and sold, and they are also the hypothetical person having ordinary skill in the art of the '486 patent. The Recon Plate Guide contains no restrictions on distribution or any other indications that the Recon Plate Guide is confidential. Accordingly, the Recon Plate Guide was sufficiently accessible to those concerned with the art to constitute a printed publication and constitutes prior

art to the '486 patent. The Recon Plate Guide is not of record in the prosecution history of the '486 patent application.

2. The Recon Plate Guide Disclosure

The Recon Plate Guide raises a substantial new question of patentability not raised during prosecution or in the *Ex parte* Reexamination. The Recon Plate Guide discloses the following key teachings:

- a bone plate adapted to receive both non-locking compression screws and locking (fixed-angle) screws (Recon Plate Guide); and
- the installation of either a locking screw or a non-locking screw as the first fastener (Recon Plate Guide).

The Recon Plate Guide describes, *inter alia,* Synthes' Locking Reconstruction Plates ("LRP") and techniques for using those plates. The LRP has partially-threaded holes that can be used with three types of screws: 2.4 mm non-locking screws, 2.4 mm locking screws, and 3.0 mm locking screws. *See* Recon Plate Guide at 1. These screws are shown below.

2.4 mm Locking Screw | 2.4 mm (non-locking) Screw | 3.0 mm Locking Screw

Id. As noted above, the plate includes "threaded plate holes," *id.*, that "accept both 2.4 mm and 3.0 mm locking screws for optimal fixation," and "2.4 mm standard screws for greater screw angulation and compression." *Id.* Thus, the locking reconstruction plate allows the surgeon to install fasteners to obtain both compression and fixation at different holes through the same plate.

The Recon Plate Guide discloses a technique for using the LRP in which the fracture is exposed, *id.* at 2, and the plate is contoured, placed over the bone, and installed using screws. *Id.*

at 2-4. The Recon Plate Guide states that the first screw is installed by "[i]nsert[ing] the proper length 3.0 mm locking screw, or 2.4 mm standard screw through the plate and tighten[ing] until secure." *Id.* Thus, either a standard (compression) or locking screw can be inserted first. Next, the remaining screws are inserted. *Id.* The Recon Plate Guide notes that it may be desirable to install 3.0 mm locking screws in osteoporotic bone, *id.* at 3, and that bone fragments can be compressed (lagged) together using angulated 2.4 mm screws. *Id.* at 4. Thus, the Recon Plate Guide suggests to the person of ordinary skill in the art that either or both types of screw can be installed in the same plate, depending on the use of the screw and the bone conditions and either type of screw can be the first one that is installed. In fact, it was known to install locking and non-locking screws in the same bone plate — and in particular in mandibular reconstruction plates like those shown in the Recon Plate Guide — a shown in U.S. Patent No. 4,484,570 to Sutter. *See* Sutter, Fig. 8. In view of the foregoing, the Recon Plate Guide renders obvious the methods claimed in the '486 patent.

3. The Recon Plate Guide Raises Substantial New Questions of Patentability

The Recon Plate Guide raises new, non-cumulative technological teachings that were not previously considered and discussed on the record during prosecution of the '486 patent or in the *Ex parte* Reexamination. As explained above, claim 10 (pending as application claim 18) was rejected *solely* over Traumatology Orthop, and was overcome because Traumatology Orthop was argued not to disclose the recited step of installing "the at least one first fastener ... before the at least one second fastener."[9] In contrast to the reference discussed on the record, the Recon Plate Guide:

[9] The plates and screws shown in the Recon Plate Guide appear to be similar to the devices shown in U.S. Patent No. 5,709,686 to Talos, which was discussed during prosection

- discloses a bone plate adapted to receive either a compression screw or a fixed-angle screw in any of its holes;
- discloses, in a surgical guide format, a method for using a bone plate in which ether a compression screw or a fixed-angle locking screw may be installed first, thereby teaching the claimed order of fixation; and
- describes the benefits of different kinds of screws being used to address different kinds of bone conditions;

As such, the Recon Plate Guide raises a substantially different question of patentability over the references applied during original examination of the '486 patent. *See* 35 U.S.C. § 312; *and* M.P.E.P. § 2616.

The Recon Plate Guide also raises a new question of patentability over the prior art cited in the *Ex parte* Reexamination. For example, unlike the DRP Guide, the Recon Plate Guide:

- describes a threaded screw as the second, fixed-angle fastener (the DRP Guide discloses a threaded-head locking pin); and
- discloses a bone plate adapted to receive either a compression screw or a fixed-angle screw in any of its holes making it possible to provide any kind of hybrid arrangement of locking and non-locking screws that is desired to address the underlying bone conditions.

In contrast to the Koval Article, the Recon Plate Guide:

- describes a threaded screw having a separate and distinct threaded head (the Koval Article discloses a conventional screw that engages a welded-in nut via the same set of threads that engage the bone);
- describes a bone plate having threads formed in the plate, instead of being formed in separate nuts that are welded to the plate; and
- discloses a bone plate adapted to receive either a compression screw or a fixed-angle screw in any of its holes making it possible to provide any kind of hybrid arrangement of locking and non-locking screws that is desired to address the underlying bone conditions.

---

solely in relation to the system claims. There is no indication or evidence that the Examiner appreciated the relevance of teachings in Talos with respect to the method claims during original prosecution.

Finally, in contrast to the Haas Article, the Recon Plate Guide:

- describes a compression screw that presses the plate to the bone to hold a fracture reduction (the Haas Article does not discuss non-fixed angle screws being used in the shown plate); and
- discloses a bone plate adapted to receive either a compression screw or a fixed-angle screw in any of its holes making it possible to provide any kind of hybrid arrangement of locking and non-locking screws that is desired to address the underlying bone conditions.

As explained above, the Recon Plate Guide discloses a number of new, non-cumulative technological teachings that are relevant to patentability but that are relevant to patentability but that are not found in the prior art considered during original examination or in the *Ex parte* Reexamination. Therefore, the Recon Plate Guide raises a question of patentability that is substantially different from the questions previously raised. *See* 35 U.S.C. § 312; *and* M.P.E.P. § 2616.

A substantial new question of patentability as to claims 10-13 is therefore raised by the Recon Plate Guide

'486 PATENT SYSTEM CLAIMS

G. SUBSTANTIAL NEW QUESTIONS OF PATENTABILITY STEMMING FROM MÜCKTER

1. Mückter Is Prior Art

WO 99/25266 to Mückter ("Mückter") was published on May 27, 1999. It is therefore prior art under 35 U.S.C. § 102(a) with respect to subject matter included in the '486 patent provisional application (60/153,239), and prior art under 35 U.S.C. § 102(b) with respect to subject matter added in the '486 patent utility application (09/660,287). U.S. Patent No. 6,468,278 B1 is the national stage filing of WO 99/25266 in the United States, and is an English-

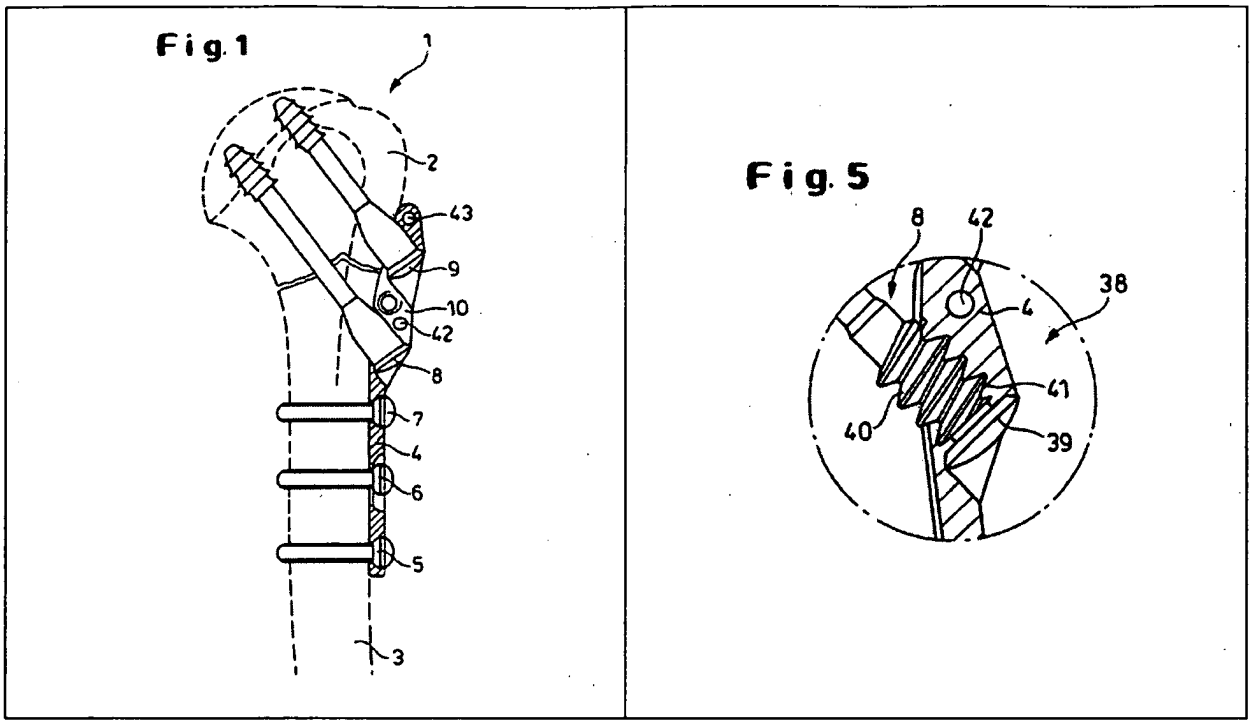
language equivalent of WO 99/25266. Neither WO 99/25266 nor U.S. Patent No. 6,468,278 B1 are of record in the prosecution history of the '486 patent application.

2. **The Mückter Disclosure**

Mückter raises a substantial new question of patentability not addressed in the original prosecution or the *Ex parte* Reexamination. For example, Mückter discloses the following key features not found in the prior art discussed on the record during original prosecution:

- A bone plating system having a shaft configured and dimensioned to conform to a bone diaphysis and a head configured and dimensioned to conform to a bone metaphysis;
- threaded first holes through the bone plate head and corresponding threaded-head screws;
- unthreaded second holes through the bone plate shaft and corresponding screws; and
- a longitudinally elongated screw hole having an angled edge to displace the bone plate when engaged by the head of a screw.

Referring to Figure 1, reproduced below, Mückter discloses a bone plate having upper and bone contacting surfaces, a head portion that conforms to a metaphysis of a bone, and a shaft portion that conform to a diaphysis of a bone. *See* Mückter, Fig. 1. The Mückter plate includes conventional compression screws through the shaft, *id.* at col. 3, ll. 10-11, and locking screws through the plate head that are held at a fixed angular position. *Id.* at col. 3, ll. 38-49 (describing screws 8 and 9). Mückter states that the locking screws (screws 8 and 9) in Figure 1 may be replaced by screws that thread into corresponding threaded holes through the plate, as shown in Figure 5. *Id.* at col. 3, l. 61 - col. 4, l. 8 ("the screw seat 41 in plate 4, which serves as a guide, is designed with a corresponding inner thread."); *and* Fig. 5.



Mückter includes all of the elements recited in a number of the '486 patent system claims. For example, Mückter includes all of the elements of claim 1, including the "thread having a head," *id.*, Fig. 5 (screw 8 in Fig. 5 has a head 39 with a thread 40 associated with it), a "head portion configured and dimensioned to conform to a metaphysis of a bone", *id.*, Fig. 1, and "the head portion has only first plate holes." *Id.* Mückter also discloses various other features of the '486 patent claims, such as a cannulated screw (claim 4), *id.* at col. 4, ll. 28-31, an elongated hole with an inclined edge to displace the plate when engaged by the screw head (claim 9), *id.* at col. 3, ll. 8-10 *and* Fig. 1, a head that flares out from the shaft (claim 14), *id.* at Fig. 1, and suture holes through the plate head (claim 15). *See, e.g., id.* at col. 2, ll. 18-22 (describing holes for PDS cords to reattach tubercula); col. 4, ll. 13-16 (same) *and* Figs. 1 and 5 (showing PDS cord holes 42 and 43).

3. Mückter Raises Substantial New Questions of Patentability

Mückter raises new, non-cumulative technological teachings that were not previously considered and discussed on the record during prosecution of the '486 patent or in the *Ex parte* Reexamination. During original prosecution, the Examiner applied three primary references against the '486 patent application system claims: Talos (U.S. Pat. No. 5,709,686), Gotfried (U.S. Pat. No. 5,429,641) and Bono (U.S. Pat. No. 6,129,730). Unlike these references, Mückter discloses all of the features of claims 1, 4, 9, 14 and 15. In fact, Mückter includes, in a single reference, a number of the features that were missing from the cited art and relied upon to allow the '486 patent claims. Indeed, had Mückter been applied rather than Gotfried, for example, it is clear that none of the '486 patent system claims would have been allowed. For example, Mückter includes the following teachings that are not found in Talos:

- A bone plate with a head portion and a shaft portion that are configured and dimensioned to conform to the metaphysis and diaphysis of the femur bone, respectively, as recited in all of the claims (Talos is a straight plate);
- a plate with a head that flares out from the shaft, as recited in claim 14, to conform to the flared shape of the bone metaphysis;
- a combination of threaded and unthreaded holes (Talos only discloses partially-threaded holes);
- simultaneous implantation of locking and non-locking screws (Talos is capable of such use, but does not describe it);
- a bone plate with a head having only threaded "first plate holes" as recited in claim 1;
- cannulated, locking bone plate screws, as recited in claim 4; and
- suture holes through the plate head, as recited in claim 15.

Mückter also includes critical missing elements that were are not found in Gotfried, such as:

- A bone plate with a head portion and a shaft portion that are configured and dimensioned to conform to the metaphysis and diaphysis of the bone, respectively (Gotfried is a straight plate having a bent end for attaching a holding tool, but there are no plate fixation holes in the bent end, and the bent end does not conform to the bone);

- a plate with a head that flares out from the shaft to conform to the flared shape of the bone metaphysis;
- a bone plate with a head having only threaded "first plate holes;"
- a bone plate with DCU holes along the shaft that can be used to axially displace the plate; and
- cannulated, locking bone plate screws.

In addition, Mückter includes the following teachings that are not found in Bono:

- A bone plate with a head portion and a shaft portion that are configured and dimensioned to conform to the metaphysis and diaphysis of the femur bone, respectively (Bono is a spine plate, and does not have these features);
- a plate with a head that flares out from the shaft to conform to the flared shape of the bone metaphysis;
- a bone plate with threads formed directly in the plate holes (Bono discloses holes into which threaded bushings are inserted, which, according to Synthes, is a relevant distinguishing feature);
- simultaneous implantation of locking and non-locking screws (Bono has slots that could receive non-locking screws, but no screws are shown in those slots);
- cannulated, locking bone plate screws; and
- suture holes through the plate head.

Mückter also discloses, in a single reference, many of the features that either are not found in *any* of the prior art discussed on the record, or were found only partially disclosed in secondary references.

Mückter also provides new, non-cumulative technological teachings that are not present in the prior art cited in the *Ex parte* Reexamination. For example, Mückter includes the following teachings that are not found in the DRP Guide:

- A bone plate with a head portion and a shaft portion that are configured and dimensioned to conform to the metaphysis and diaphysis of the femur bone, respectively (the DRP Guide is a plate for an arm bone)10;

[10] It is believed that Synthes will attempt to rely on the DRP Guide's disclosure of use in an arm bone, but not a leg bone, as a feature that somehow distinguishes the claims over the prior art. Requester disagrees with any such argument, but to the extent Synthes relies on it, this distinction is relevant to the new question of patentability analysis.

- A locking screw having a thread on the screw shaft to engage the bone (The DRP Guide discloses a threaded-head locking pin);
- cannulated, locking bone plate screws; and
- suture holes through the plate head.

Similarly, Mückter includes the following teachings that are not found in the Koval Article:

- A bone plate with threads formed directly in the plate holes;
- a bone plate with a head having only threaded "first plate holes" as recited in claim 1;
- cannulated, locking bone plate screws; and
- suture holes through the plate head.[11]

Finally, Mückter includes the following teachings that are not found in the Haas Article:

- a bone plate having a combination of threaded screw holes an non-threaded screw holes;
- a bone plate having DCU holes along the shaft that can be used to axially displace the plate; and
- cannulated, locking bone plate screws.

In view of at least the foregoing, it is clear that Mückter includes additional subject matter beyond the references considered during original prosecution and identified in the *Ex parte* Reexamination, and presents a substantially different and distinct new question of patentability over those references. *See* 35 U.S.C. § 312; *and* M.P.E.P. § 2616.

A substantial new question of patentability as to claims 1-7, 9 and 14-16 is therefore raised by Mückter.

[11] Of course, any hole the is not used to implant a screw could be used as a suture hole, but the Koval Article does not expressly discuss this inherent function, whereas Mückter specifically provides suture holes that are separate from the screw holes and describes their use as such.

H. SUBSTANTIAL NEW QUESTIONS OF PATENTABILITY STEMMING FROM THE K982222 SUMMARY

1. The K982222 Summary Is Prior Art

Synthes, the '486 patent holder, is a manufacturer of bone plates, which are classified as medical devices and are regulated by the Food and Drug Administration ("FDA"). As such, bone plate manufacturers typically are required to submit a Premarket Notification Application to the FDA under section 510(k) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360, requesting permission to market a bone plate. This type of filing is known as a "510(k) filing," and such filings include a "Summary of Safety and Effectiveness Information" that describes the product. On June 23, 1998, Synthes submitted a 510(k) filing for a bone plate system called the "DFP System." This filing received a unique identifier — "K982222" — from the FDA. The FDA published the K982222 "Summary of Safety and Effectiveness Information" ("K982222") on its website no later than August 26, 1998.

The K982222 Summary is prior art under 35 U.S.C. § 102(b) because it is a printed publication that was available to the public more than one year before the earliest filing date of the '744 patent. To determine the date the K982222 Summary was published, Requester submitted a Freedom of Information Act ("FOIA") asking the FDA to indicate the date on which the K982222 Summary was available on the FDA's public web server. In response, the FDA certified that "510(K) Number K982222 was uploaded to the FDA's FTP web server on August 26,1998, making 510(k) Number K82222 accessible to the public through the FDA website as of that date." *See* Exhibit C. Therefore, the K982222 Summary qualifies as a publicly available printed publication that is prior art to the '744 patent.

The K982222 Summary is not of record in the prosecution history of the '744 patent application.

2. The K982222 Disclosure

K982222 discloses a bone plate with several new, non-cumulative technological teachings that were not previously considered and discussed on the record during prosecution of the '486 patent or in the *Ex parte* Reexamination. Specifically, K982222 discloses a bone "plate and screw system" with the following key features:

- A condylar buttress plate with a head portion and a shaft portion12 ("The plate is available with an anatomically curved head") ("The DFP shaft features ...");
- Threaded locking plate holes ("four of the six holes are threaded")
- A combination of threaded and unthreaded plate holes ("the head of the plate has six screw holes; four of the six holes are threaded ... the two posterior holes are non-threaded");
- Locking screws that rigidly lock to the plate ("The threads just below the head of the screw engage with the threaded holes of the DFP. This engagement of the screw to the plate creates a locked, fixed angle construct.");
- Self-drilling, self-tapping, and cannulated locking screws for use in the threaded holes ("The 7.3 mm locking screws feature self-drilling and self-tapping tips, are cannulated, ...");
- Non-locking screws for use in the unthreaded holes in the head or shaft ("6.5 mm cancellous screws or 7.0/7.3 mm cannulated screws" and the "4.5 mm cortex screws");
- A plate with a limited contact profile ("The DFP shaft features ... a limited-contact profile"); and
- Elongated "Dynamic Compression Unit" holes ("The DFP shaft features dynamic compression unit (DCU) screw holes").

See K982222.

As such, K982222 describes almost every element recited in the '486 patent system claims, and is highly relevant to patentability. Indeed, many of the '486 patent claims avoid reading directly on Synthes' prior K982222 document by the narrowest of margins.

[12] K982222 describes its contoured head almost exactly like the '486 patent describes its own head. *See* '486 patent, col. 6, ll. 54-56 ("head portion 60 of bone plate 50 is contoured only in the longitudinal direction for a more anatomical fit.")

For example, K982222 also includes each and every element recited in claim 14 of the '486 patent. As explained above, K982222 discloses the recited bone plate having threaded "first holes" and unthreaded "second holes," as well as a head that conforms to the bone metaphysis and a shaft that conforms to the bone diaphysis. *Id.* K982222 also includes the "first screw" and "second screw" limitations. The "first screw" in K982222 is the locking screw, which has a "head with a thread" (the thread is "just below the head" in K982222, and therefore the head is provided with a thread[13]). The "second screw" in K982222 is the "6.5 mm cancellous screws or 7.0/7.3 mm cannulated screws" and the "4.5 mm cortex screws." *Id.* Finally, K982222 states that the head is "anatomically curved" and "is intended for buttressing multifragmentary distal femur fractures," and therefore the head of the plate must flare outward from the shaft to be "anatomically curved" to fit the distal femur, which has a flared metaphysis. *Id.* The remaining system claims of the '486 patent vary only slightly from claim 14, and all of these claims are obvious in view of K982222.

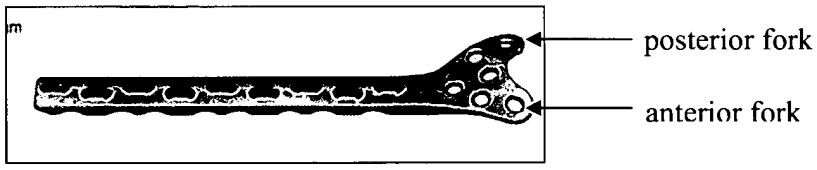
With regard to claims 8, 16 and 18, Requester relies on Synthes' 1997 product catalog to help explain the contents of K982222.[14] K982222 refers the reader to "Synthes Condylar Buttress Plates" as a predicate device. The Synthes Condylar Buttress Plates are described in the Synthes 1997 Catalog. *See, e.g.*, Synthes 1997 Catalog, at 2a-20 and 2a-24. The Synthes 1997

[13] The '486 patent states that: "any surgical screw that has a head 22 with threads 24 can be used as long as head 22 is of an appropriate size and geometry for select plate holes of the bone plate and threads 24 mate with the threads of the plate holes." '486 Patent, col. 4, ll. 30-34. As such, the locking "first screw" claimed in the '486 patent can be of the type illustrated in the patent (which has an enlarged head portion), or *any other type* in which the threads mate with the threads of the plate hole. The claims and '486 specification do *not* require the threads to *surround* the head, they just require the head to "*have*" threads.

[14] Reliance on additional references is proper to explain the contents of a reference raising a substantial new question of patentability. *See* MPEP §§ 2217(II), 2258(I)(E) and 2124.

Catalog bears the date "3/97," and Synthes has confirmed that it was made available to the relevant public. *See* Exhibit D, (Haag 5/28/08 Dep.) at 60-65 (Synthes' corporate representative testifying that "[t]his document would indicate the printing date of March 1997" and confirming public availability to Synthes' customers). Thus, the 1997 Synthes Catalog is prior art under 35 U.S.C. § 102(b).[15]

As shown in the below illustration from the Synthes 1997 Catalog, Synthes' Titanium LC-DCP Condylar Buttress Plate has a head that has "a curved surface, ... an anterior fork substantially parallel to an anterior side of the shaft portion, and ... a posterior fork extending out from a posterior side of the shaft portion," as recited in claim 16. This plate also includes arched cutouts along the lower surface that provide the "trapezoidal shaped cross section ... for minimizing contact between the bone and the bone-contacting surface" recited in claims 8 and 18.



Thus, the Synthes 1997 Catalog explains that the "Synthes Condylar Buttress Plates" described as the "predicate device" to K982222 has the head shape recited in claim 16 and the profile described in claims 8 and 18. To the extent K982222 somehow does not include this

[15] "[P]ublic accessibility has been called the touchstone in determining whether a reference constitutes a 'printed publication' bar under 35 U.S.C. § 102(b)." *SRI Int'l, Inc. v. Internet Sec. Sys., Inc.*, 511 F.3d 1186, 1194 (Fed. Cir. 2008) (en banc). "[I]f accessibility is proved, there is no requirement to show that particular members of the public actually received the information." *Constant v. Advanced Micro Devices, Inc.*, 848 F.2d 1560, 1569 (Fed. Cir. 1988).

structure, it would have been obvious to modify it to include the structure shown in the Synthes 1997 Catalog because K982222 directs the reader to such products as a "predicate device."

3. K982222 Raises Substantial New Questions of Patentability

K982222 raises new, non-cumulative technological teachings that were not previously considered and discussed on the record during prosecution of the '486 patent or in the *Ex parte* Reexamination. During original prosecution, the Examiner applied three primary references against the '486 application claims: Talos (U.S. Pat. No. 5,709,686), Gotfried (U.S. Pat. No. 5,429,641), and Bono (U.S. Pat. No. 6,129,730). At the time of original prosecution, the Examiner did not have the benefit of Synthes' K982222 document, which teaches all of the features described above (see listed items (a)-(h)), and more, and is more directly on point than any single reference or combination of references applied during original prosecution. For example, K982222 includes the following teachings that are not found in Talos:

- A bone plate with a head portion and a shaft portion that are configured and dimensioned to conform to the metaphysis and diaphysis of the femur bone, respectively (Talos is a straight plate);
- A combination of threaded and unthreaded holes (Talos only discloses partially-threaded holes);
- simultaneous implantation of locking and non-locking screws (Talos is capable of such use, but does not describe it);
- a bone plate with a head having threaded holes, in combination with a DCU hole along the shaft (as described in '486 patent claim 9) that can be used to axially displace the plate;
- self-drilling screws;
- self-tapping screws; and
- cannulated, locking bone plate screws.

Similarly, K982222 includes the following teachings that are not found in Gotfried:

- A bone plate with a head portion and a shaft portion that are configured and dimensioned to conform to the metaphysis and diaphysis of the femur bone, respectively (Gotfried is a straight plate having a bent end for attaching a holding tool, but there are *no plate fixation holes in the bent end*, and the bent end *does not conform to the bone*);
- a bone plate with a head having threaded holes, and DCU holes along the shaft (as described in '486 patent claim 9) that can be used to axially displace the plate;
- a bone plate having a limited contact profile;
- self-drilling screws;
- self-tapping screws; and
- cannulated, locking bone plate screws.

In addition, K982222 includes the following teachings that are not found in Bono:

- A bone plate with a head portion and a shaft portion that are configured and dimensioned to conform to the metaphysis and diaphysis of the femur bone, respectively (Bono is a spine plate, and does not have these features);
- a bone plate with threads formed directly in the plate holes (Bono discloses holes into which threaded bushings are inserted, which, according to Synthes, is a relevant distinguishing feature);
- simultaneous implantation of locking and non-locking screws (Bono has slots that could receive non-locking screws, but no screws are shown in those slots);
- a bone plate with a head having threaded holes, and DCU holes along the shaft;
- self-drilling screws; and
- cannulated, locking bone plate screws.

K982222 also discloses, in a single reference, many of the features that either are not found in *any* of the prior art discussed on the record, or were found only partially disclosed in secondary references.

K982222 also provides new, non-cumulative technological teachings that are not present in the prior art cited in the *Ex parte* Reexamination. For example, K982222 includes the following teachings that are not found in the DRP Guide:

- A bone plate with a head portion and a shaft portion that are configured and dimensioned to conform to the metaphysis and diaphysis of the femur bone, respectively (the DRP Guide is a plate for an arm bone);
- specific reference to "Synthes Condylar Buttress Plates," which disclose a femur-style plate unlike the Distal Radius Plate;
- a locking screw having a thread on the screw shaft to engage the bone (The DRP Guide discloses a threaded-head locking pin);
- self-drilling locking screws;
- self-tapping locking screws; and
- cannulated, locking bone plate screws.

Similarly, K982222 includes the following teachings that are not found in the Koval Article:

- A bone plate with threads formed directly in the plate holes (the Koval Article discloses holes into which threaded nuts are welded, which, according to Synthes, is a relevant distinguishing feature);
- a bone plate having a limited contact profile;
- locking screws with a head having a thread that is different from the remaining non-locking screws (the Koval Article uses only discloses compression screws, and Synthes has taken the position that the Koval Article does not disclose any kind of locking screw); and
- cannulated, locking bone plate screws.

Finally, K982222 includes the following teachings that are not found in the Haas Article:

- a bone plate having a combination of threaded screw holes an non-threaded screw holes;
- a bone plate having DCU holes along the shaft (as described in '486 patent claim 9) that can be used to axially displace the plate;
- a bone plate having a limited contact profile; and
- cannulated, locking bone plate screws.

In view of at least the foregoing, it is clear that K982222 includes additional subject matter beyond the references considered during original prosecution and identified in the *Ex parte* Reexamination, and presents a substantially different and distinct new question of patentability over those references. *See* 35 U.S.C. § 312; *and* M.P.E.P. § 2616.

A substantial new question of patentability as to claims 1-9 and 14-18 is therefore raised by K982222

I. SUBSTANTIAL NEW QUESTIONS OF PATENTABILITY STEMMING FROM THE SCHUHLI GUIDE

1. The Schuhli Guide Is Prior Art

As explained above with respect to '486 patent claims 10-13, Synthes' Schuhli Guide is a printed publication that qualifies as prior art under 35 U.S.C. § 102(b), and was not of record in the prosecution history of the '486 patent application.

2. The Schuhli Guide Disclosure

The Schuhli Guide raises a substantial new question of patentability not raised during prosecution or in the *Ex parte* Reexamination. The Schuhli Guide discloses the following key features:

- a bone plate having head and shaft portions that are configured to conform to the metaphysis and diaphysis of a bone;
- a combination of locking and non-locking screws used to address different parts of the underlying bone; and
- motivation and teaching to place locking screws at any location on the bone plate.

As explained above, the Schuhli Guide describes a threaded lock washer that fits into the holes through standard Dynamic Compression Plates ("DCP") and Limited Contact Dynamic Compression Plates ("LC-DCP"). *See* Schuhli Guide, inside cover. The Schuhli Washer "fits between the underside of the plate and the bone," and locks the screw to the plate to allow "the construct to act as a fixed-angle device." *Id.* The Schuhli Guide discloses Schuhli Washers being located at several locations on the bone plate, including the head, *id.* at 5, and the shaft. *Id.* at 2. In fact, the Schuhli Guide teaches that the locking Schuhli Washers can be used in "osteoporotic bone, where purchase of the screw threads is diminished and pullout is a concern,"

and "to secure a plate to the bone where there is a cortical defect."[16] *Id.* As such, the Schuhli Guide teaches that a fixed-angle device such as a locking washer, can be used wherever necessary or desirable to address the condition of the underlying bone. Thus, the Schuhli Guide, alone, renders it obvious to use only locking fasteners in the head of a bone plate (claim 1) or to use a mix of locking and non-locking fasteners in the bone plate shaft (claim 17). The Schuhli Guide also teaches a other features recited in the claims, such as a shaft having a trapezoidal shaped cross section (claims 8 and 18), *id.*, cover illustration, and the use of an elongated "DCU" hole (claim 9). *Id.*, at 1 (describing use with "Limited Contact Dynamic Compression Plate (LC-DCP*)). To help explain the contents of the Schuhli Guide, Requester relies on the Manual of Internal Fixation. In particular, the Manual of Internal Fixation explains that Dynamic Compression Plates include elongated DCU holes as recited in claim 9, *see* Manual of Internal Fixation, at 240-251 (illustrating holes and describing use), and that the LC-DCP plate has cutouts that provide a "trapezoid cross section" between screw holes. *Id*, at Fig. 3.40A *and* p. 242 (describing Fig. 3.40A). As explained below and in the attached claim charts, it would have been obvious to combine the Schuhli Guide with a number of references to arrive at the claimed subject matter.

3. The Schuhli Guide Disclosure in view of Haas Raises Substantial New Questions of Patentability

The Schuhli Guide raises new, non-cumulative technological teachings that were not previously considered and discussed on the record during prosecution of the '486 patent or in the *Ex parte* Reexamination. For example, the Schuhli Guide includes the following teachings that are not found in Talos:

[16] A cortical defect can exist, for example, where the bone cortex (wall) is missing, damaged, or severely comminuted.

- A bone plate with a head portion and a shaft portion that are configured and dimensioned to conform to the metaphysis and diaphysis of the femur bone, respectively (Talos is a straight plate);
- a plate with a head that flares out from the shaft to conform to the flared shape of the bone metaphysis;
- a combination of threaded and unthreaded holes17 (Talos only discloses partially-threaded holes);
- simultaneous implantation of locking and non-locking screws (Talos is capable of such use, but does not describe it);
- the teaching that is it beneficial to use locking features at any location on a bone plate; and
- a bone plate with a head having threaded holes, in combination with a DCU hole along the shaft (as described in '486 patent claim 9) that can be used to axially displace the plate.

Similarly, the Schuhli Guide includes the following teachings that are not found in Gotfried:

- A bone plate with a head portion and a shaft portion that are configured and dimensioned to conform to the metaphysis and diaphysis of the femur bone, respectively (Gotfried is a straight plate having a bent end for attaching a holding tool, but there are no plate fixation holes in the bent end, and the bent end does not conform to the bone);
- a plate with a head that flares out from the shaft to conform to the flared shape of the bone metaphysis;
- a bone plate with a head having threaded holes, and DCU holes along the shaft (as described in '486 patent claim 9) that can be used to axially displace the plate;
- the teaching that is it beneficial to use locking features at any location on a bone plate; and
- a bone plate having a limited contact profile.

[17] The '486 patent claims do not specifically require the threads to be formed in the plate — they merely require the first holes to "have" a thread. As such, a configuration in which a threaded insert in placed in an unthreaded hole would satisfy the recited "first hole ... having a thread." *See* M.P.E.P. § 2111 (claims given broadest reasonable interpretation).

In addition, the Schuhli Guide includes the following teachings that are not found in Bono:

- A bone plate with a head portion and a shaft portion that are configured and dimensioned to conform to the metaphysis and diaphysis of the femur bone, respectively (Bono is a spine plate, and does not have these features);
- a plate with a head that flares out from the shaft to conform to the flared shape of the bone metaphysis;
- simultaneous implantation of locking and non-locking screws (Bono has slots that could receive non-locking screws, but no screws are shown in those slots);
- the teaching that is it beneficial to use locking features at any location on a bone plate; and
- a bone plate with a head having threaded holes, and DCU holes along the shaft.

The Schuhli Guide also provides new, non-cumulative technological teachings that are not present in the prior art cited in the *Ex parte* Reexamination. For example, the Schuhli Guide includes the following teachings that are not found in the DRP Guide:

- A bone plate with a head portion and a shaft portion that are configured and dimensioned to conform to the metaphysis and diaphysis of the femur bone, respectively (the DRP Guide is a plate for an arm bone);
- a bone plate having a locking screw located along the bone plate shaft suggesting the structure claimed in claim 17 (the DRP Guide only discloses locking fasteners located in the plate head);
- the demonstrated interchangeability of the use of locking features in various different kinds of bones, as shown in the various Schuhli Guide case examples (the DRP Guide is shown only on one general bone type);
- the teaching that is it beneficial to use locking features at any location on a bone plate; and
- a locking screw having a thread on the screw shaft to engage the bone (The DRP Guide discloses a threaded-head locking *pin*).

Similarly, the Schuhli Guide includes the following teachings that are not found in the Koval Article:

- A bone plate having a locking screw located along the bone plate shaft suggesting the structure claimed in claim 17 (the Koval Article only discloses locking screws located in the plate head);

- a bone plate having a limited contact profile; and
- the demonstrated interchangeability of the use of locking features in various different kinds of bones, as shown in the various Schuhli Guide case examples (the Koval Article shows only a femur application).

Finally, the Schuhli Guide includes the following teachings that are not found in the Haas Article:

- A bone plate having a combination of locking fasteners and non-locking fasteners being implanted in the same plate (the Haas Article does not discuss the use of non-locking fasteners);
- a bone plate having DCU holes along the shaft (as described in '486 patent claim 9) that can be used to axially displace the plate;
- the demonstrated interchangeability of the use of locking features in various different kinds of bones, as shown in the various Schuhli Guide case examples (the Koval Article shows only a femur application);
- the teaching that is it beneficial to use locking features at any location on a bone plate; and
- a bone plate having a limited contact profile.

In view of the foregoing, the Schuhli Guide clearly raises a substantial new question of patentability over the references discussed on the record during prosecution and raised in the *Ex parte* Reexamination. *See* 35 U.S.C. § 312; *and* M.P.E.P. § 2616.

A substantial new question of patentability as to claims 1-9 and 14-18 is therefore raised by the Schuhli Guide in view of Haas.

J. SUBSTANTIAL NEW QUESTIONS OF PATENTABILITY STEMMING FROM KASSAB

1. The Kassab Article Is Prior Art

As explained above, the Kassab Article qualifies as prior art to the '486 patent under 35 U.S.C. § 102(b), and was not of record in the prosecution history of the '486 patent application.

2. The Kassab Article Disclosure

The Kassab Article provides a substantial new question of patentability not raised during prosecution or in the *Ex parte* Reexamination. In particular, the Kassab Article discloses:

- a bone plate having head and shaft portions that are configured to conform to the metaphysis and diaphysis of a bone;
- the shaft portion of the plate has both locking and non-locking screws; and
- explicit teaching to place locking screws at any location on the bone plate.

The Kassab Article describes a number of surgical procedures in which a locking nuts (in particular, Schuhli nuts) are used on the underside of a bone plate "to lock a 4.5-mm bone screw to the Dynamic Compression Plate (DCP), (Synthes USA) independent of bony contact with the plate." Kassab, p. 86. The Kassab Article describes three primary uses for locking nuts: when the bone structure was compromised due to bone loss or a previously-removed screw, where there are high mechanical loads, and in severely osteoporotic bone. *Id.* at 87. The Kassab Article further noted that locking nuts like the Schuhli nut can be used "to create a fixed angle relationship at any screw hole." *Id.* at 91.

In one procedure, described with reference to Figures 3A-D, the surgeon removed a dynamic screw plate (shown implanted in Fig. 3A) and replaced it with a 95 degree blade plate. *Id.*, Figs. 3B-D and description thereof. The Kassab Article explains that the 95 degree blade plate is installed and "after tensioning," a schuhli nut is used "at distal screw Number 4 on the proximal side of the osteotomy." *Id.* As shown in Figures 3B-D, the Schuhli nut is located along the plate shaft. Thus, the Kassab Article discloses virtually every limitation of '486 patent claim 17, and any missing features would be obvious to add, as explained below and in the attached claim charts.

3. Kassab Raises Substantial New Questions of Patentability

The Kassab Article raises new, non-cumulative technological teachings that were not previously considered and discussed on the record during prosecution of the '486 patent or in the *Ex parte* Reexamination. During original prosecution, the Examiner relied on Talos (U.S. Pat. No. 5,709,686), Gotfried (U.S. Pat. No. 5,429,641), and Bono (U.S. Pat. No. 6,129,730) as prior

art against the '486 system claims. The Kassab Article include new teachings over these references. For example, the Kassab Article includes the following teachings that are not found in Talos:

- A bone plate with a head portion and a shaft portion that are configured and dimensioned to conform to the metaphysis and diaphysis of the femur bone, respectively (Talos is a straight plate);
- a plate with a head that flares out from the shaft to conform to the flared shape of the bone metaphysis;
- simultaneous implantation of locking and non-locking screws (Talos is capable of such use, but does not describe it); and
- the teaching that is it beneficial to use locking features at any location on a bone plate to address the underlying bone condition.

Similarly, the Kassab Article includes the following teachings that are not found in Gotfried:

- A bone plate with a head portion and a shaft portion that are configured and dimensioned to conform to the metaphysis and diaphysis of the femur bone, respectively (Gotfried is a straight plate having a bent end for attaching a holding tool, but there are no plate fixation holes in the bent end, and the bent end does not conform to the bone), and in particular such a plate having a combination of locking and non-locking screws along the shaft as recited in claim 17;
- a plate with a head that flares out from the shaft to conform to the flared shape of the bone metaphysis; and
- the teaching that is it beneficial to use locking features at any location on a bone plate to address the underlying bone condition.

In addition, the Kassab Article includes the following teachings that are not found in Bono:

- A bone plate with a head portion and a shaft portion that are configured and dimensioned to conform to the metaphysis and diaphysis of the femur bone, respectively (Bono is a spine plate, and does not have these features);
- a plate with a head that flares out from the shaft to conform to the flared shape of the bone metaphysis;
- a bone plate having a combination of locking and non-locking screws along the shaft as recited in claim 17;

- simultaneous implantation of locking and non-locking screws (Bono has slots that could receive non-locking screws, but no screws are shown in those slots); and
- the teaching that is it beneficial to use locking features at any location on a bone plate to address the underlying bone condition.

The Kassab Article also provides new, non-cumulative technological teachings that are not present in the prior art cited in the *Ex parte* Reexamination. For example, the Kassab Article includes the following teachings that are not found in the DRP Guide:

- A bone plate with a head portion and a shaft portion that are configured and dimensioned to conform to the metaphysis and diaphysis of the femur bone, respectively (the DRP Guide is a plate for an arm bone);
- a bone plate having locking and non-locking screws located along the bone plate shaft suggesting the structure claimed in claim 17 (the DRP Guide only discloses locking fasteners located in the plate head);
- the teaching that is it beneficial to use locking features at any location on a bone plate to address the underlying bone condition; and
- a locking screw having a thread on the screw shaft to engage the bone (The DRP Guide discloses a threaded-head locking *pin*).

Similarly, the Kassab Article includes the following teachings that are not found in the Koval Article:

- A bone plate having locking and non-locking screws located along the bone plate shaft suggesting the structure claimed in claim 17 (the Koval Article only discloses locking screws located in the plate head).

Finally, the Kassab Article includes the following teachings that are not found in the Haas Article:

- A bone plate having a combination of locking fasteners and non-locking fasteners being implanted in the same plate (the Haas Article does not discuss the use of non-locking fasteners), and particularly a bone plate having locking and non-locking screws located along the bone plate shaft suggesting the structure claimed in claim 17; and
- the teaching that is it beneficial to use locking features at any location on a bone plate to address the underlying bone conditions.

In view of the foregoing, the Kassab Article clearly raises a substantial new question of patentability over the references discussed on the record during prosecution and raised in the *Ex parte* Reexamination. *See* 35 U.S.C. § 312; *and* M.P.E.P. § 2616.

A substantial new question of patentability as to claim 17 is therefore raised by the Kassab Article.

K. SUBSTANTIAL NEW QUESTIONS OF PATENTABILITY STEMMING FROM THE ZIMMER AD

1. The Zimmer Ad is Prior Art

The Journal of Orthopaedic Trauma, Vol. 12, No. 5, June/July, 1998 included an advertisement from Zimmer describing and illustrating its Periarticular Plating System (the "Zimmer Ad"). The Journal of Orthopaedic Trauma is a widely distributed medical journal. Accordingly, the Zimmer Ad qualifies as a publicly available printed publication that is prior art to the '486 patent under 35 U.S.C. § 102(b). The Zimmer Ad is not of record in the prosecution history of the '486 patent application.

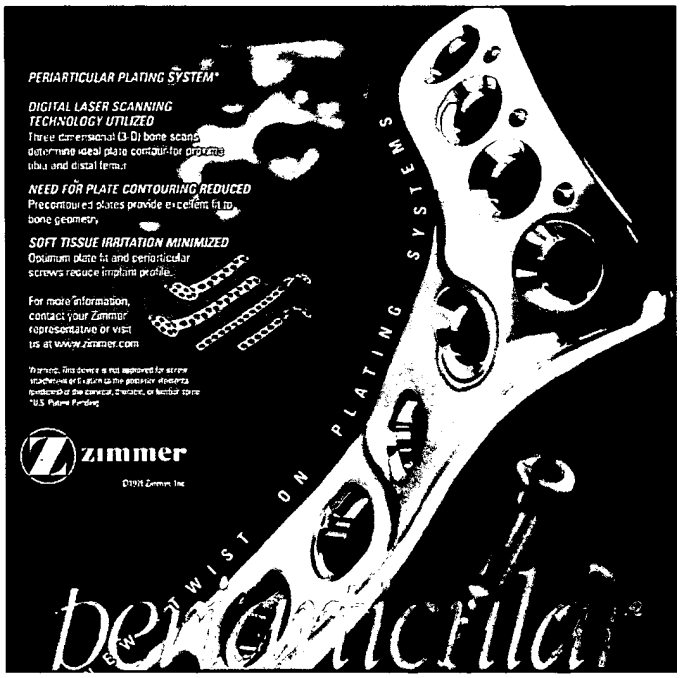
2. The Zimmer Ad Disclosure

The Zimmer Ad provides a substantial new question of patentability not raised during prosecution or in the *Ex parte* Reexamination. In particular, the Zimmer Ad discloses:

- a bone plate having head and shaft portions that are configured to conform to the metaphysis and diaphysis of a bone;
- a bone plate with the head portion flared outward from the shaft; and
- suture holes provided in the head portion of the bone plate.

The Zimmer Ad describes Zimmer's Periarticular Plating System for the proximal tibia and distal femur. *See* Zimmer Ad. These plates are advertised as being "anatomically precontoured," and the Zimmer Ad shows the plate having a head and shaft configured and dimensioned to conform to a metaphysis and a diaphysis, respectively, of a bone. *Id.* The head

portion is flared out from the shaft in two directions — first, by flaring backwards out of the plane of the shaft, and second by flaring laterally from the shaft. *Id.* As shown in the Zimmer Ad this flared shape matches the shape of the proximal tibia metaphysis, which is enlarged relative to the tibia diaphysis. As shown in the portion of the Zimmer Ad reproduced below, the flared head includes conically-tapered holes screw holes, and smaller suture holes. *Id.* The shaft includes longitudinally-elongated, ramped, unthreaded holes. *Id.* The Zimmer Ad also illustrates other shaped plates in this product line. *Id.*



The Zimmer Plate includes all of the limitations of '486 patent claims 1, 9, 14 and 15 except for the "first hole ... having a thread" and the corresponding "first screw having ... a head with a thread." As explained below and in the attached claim charts, however, it would have been obvious to any missing features of these claim in the plates shown in the Zimmer Ad. Thus, the Zimmer Ad renders a number of the '486 patent claims obvious.

3. The Zimmer Ad Raises a Substantial New Question of Patentability

The Zimmer Ad raises new, non-cumulative technological teachings that were not previously considered and discussed on the record during prosecution of the '486 patent or in the *Ex parte* Reexamination. During original prosecution, the Examiner relied on Talos (U.S. Pat. No. 5,709,686), Gotfried (U.S. Pat. No. 5,429,641), and Bono (U.S. Pat. No. 6,129,730) as prior art against the '486 system claims. In contrast to Talos, the Zimmer Ad discloses:

- A bone plate with a head portion and a shaft portion that are configured and dimensioned to conform to the metaphysis and diaphysis of the bone, respectively (Talos is a straight plate);
- a plate with a head that flares out from the shaft to conform to the flared shape of the bone metaphysis as recited in claim 14; and
- a bone plate with a head having suture holes, as recited in claim 15.

Similarly, the Zimmer Ad includes the following teachings that are not found in Gotfried:

- A bone plate with a head portion and a shaft portion that are configured and dimensioned to conform to the metaphysis and diaphysis of the bone, respectively (Gotfried is a straight plate having a bent end for attaching a holding tool, but there are no plate fixation holes in the bent end, and the bent end does not conform to the bone);
- a plate with a head that flares out from the shaft to conform to the flared shape of the bone metaphysis; and
- a bone plate with a head having suture holes.

In addition, the Zimmer Ad includes the following teachings that are not found in Bono:

- A bone plate with a head portion and a shaft portion that are configured and dimensioned to conform to the metaphysis and diaphysis of the bone, respectively (Bono is a spine plate, and does not have these features);
- a plate with a head that flares out from the shaft to conform to the flared shape of the bone metaphysis; and
- a bone plate with a head having suture holes.

The Zimmer Ad also provides new, non-cumulative technological teachings that are not present in the prior art cited in the *Ex parte* Reexamination. For example, the Zimmer Ad includes the following teachings that are not found in the DRP Guide:

- A bone plate with a head portion and a shaft portion that are configured and dimensioned to conform to the metaphysis and diaphysis of the tibia bone, respectively (the DRP Guide is a plate for an arm bone); and
- a bone plate with a head having suture holes.

Similarly, the Zimmer Ad includes the following teaching that is not found in the Koval Article:

- A bone plate with a head having suture holes.

Finally, the Zimmer Ad includes the following teachings that are not found in the Haas Article:

- A bone plate having unthreaded screw holes; and
- a bone plate having elongated holes along the shaft that can be used to axially displace the plate.

In view of at least the foregoing, it is clear that the Zimmer Ad includes additional subject matter beyond the references considered during original prosecution and identified in the *Ex parte* Reexamination, and presents a substantially different and distinct new question of patentability over those references. *See* 35 U.S.C. § 312; *and* M.P.E.P. § 2616.

A substantial new question of patentability as to claims 1-9 and 14-18 is therefore raised by the Zimmer Ad.

IV. DETAILED EXPLANATION OF THE PERTINENCE AND MANNER OF APPLYING THE CITED PRIOR ART

The following section identifies specific proposed grounds of rejection applying the prior art references listed above and on the attached PTO-1449 to the claims for which *inter partes* reexamination is requested. The details regarding each proposed rejection are set forth in the accompanying claim charts attached as Exhibits E - EE.

A. THE LAW OF ANTICIPATION

"[A] prior art reference may anticipate without disclosing a feature of the claimed invention if that missing characteristic is necessarily present, or inherent, in the single anticipating reference." *Schering Corp. v. Geneva Pharms.*, 339 F.3d 1373, 1377 (Fed. Cir. 2003). To anticipate a claimed invention, the reference must show not only all of the limitations claimed but also all of the limitations arranged or combined in the same way as recited in the claim. *See Net Moneyin v. Verisign*, 545 F.3d 1359, 1369 (Fed. Cir. 2008).

B. REJECTIONS UNDER 35 U.S.C. § 102

1. Claims 10-13 are rejected under 35 U.S.C. § 102(b) as anticipated by the Schuhli Guide

The attached Schuhli Guide § 102 Claim Chart (Exhibit E) is incorporated by reference herein. Detailed grounds for rejection are provided in the attached claim chart.

2. Claims 10-12 are rejected under 35 U.S.C. § 102(b) as being anticipated by Kassab

The attached Kassab § 102 and § 103 Claim Chart (Exhibit F) is incorporated by reference herein. Detailed grounds for rejection are provided in the attached claim chart.

3. Claims 10-13 are rejected under 35 U.S.C. § 102(b) as anticipated by Surer

The attached Surer § 102 Claim Chart (Exhibit G) is incorporated by reference herein. Detailed grounds for rejection are provided in the attached claim chart.

4. Claims 10, 12 and 13 are rejected under 35 U.S.C. § 102(b) as being anticipated by Wolter 117

The attached Wolter 117 § 102 and § 103 Claim Chart (Exhibit H) is incorporated by reference herein. Detailed grounds for rejection are provided in the attached claim chart.

5. **Claims 10 and 13 are rejected under 35 U.S.C. § 102(b) as being anticipated by Haag**

The attached Haag § 102 Claim Chart (Exhibit I) is incorporated by reference herein. Detailed grounds for rejection are provided in the attached claim chart.

6. **Claim 14 is rejected under 35 U.S.C. § 102(b) as anticipated by K982222**

The attached K982222 § 102 Claim Chart (Exhibit J) is incorporated by reference herein. Detailed grounds for rejection are provided in the attached claim chart.

7. **Claims 1, 4, 9, 14, and 15 are rejected under 35 U.S.C. § 102(a) as anticipated by Mückter**

The attached Mückter § 102 Claim Chart (Exhibit K) is incorporated by reference herein. Detailed grounds for rejection are provided in the attached claim chart.

C. THE LAW OF OBVIOUSNESS

A patent claim is invalid as obvious if the claimed subject matter would have been obvious to a person of ordinary skill in the art at the time of the invention. 35 U.S.C. § 103(a). ***The question of obviousness is a question of law*** with factual underpinnings. *Ruiz v. A.B. Chance Co.*, 357 F.3d 1270, 1275 (Fed. Cir. 2004); MPEP § 2141(II) ("Obviousness is a question of law based on underlying factual inquiries."). "Those factual underpinnings include the scope and content of the prior art, differences between the prior art and the claims at issue, and the level of ordinary skill in the art." *Dippin' Dots, Inc. v. Mosey*, 476 F.3d 1337, 1343 (Fed. Cir. 2007) (citing *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966)). The obviousness of the claimed subject matter is determined against these factors, which are often referred to as the *Graham* factors. *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966). Obviousness is evaluated on a "claim by claim" basis. *Dystar Textilfarben GmbH v. C.H. Patrick Co.*, 464 F.3d 1356, 1372 (Fed. Cir. 2006). Secondary factors of non-obviousness, such as commercial

success, a long felt but unsolved need, and failure of others, may be considered in determining whether the claimed subject matter is obvious if they are relevant. *Id.* at 17-18. Such secondary considerations, however, cannot be used to overcome a strong showing of obviousness under the *Graham* factors. *See, e.g., Leapfrog Enters., Inc. v. Fisher-Price, Inc.*, 485 F.3d 1157, 1162 (Fed. Cir. 2007); *Pfizer, Inc. v. Apotex*, 480 F.3d 1348, 1372 (Fed. Cir. 2007).

Prior to the Supreme Court's recent landmark decision in *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 415-16 (2007), a patent that combined elements from two or more prior art references was obvious only if there was some explicit *teaching, suggestion or motivation* ("TSM") to combine the references. Under the TSM test for obviousness, it was difficult to invalidate combination patents as being obvious because it was often impossible to find an express teaching, suggestion, or motivation to combine the known prior art elements. The Supreme Court's *KSR* decision did away with the rigid application of the TSM test and instead adopted an "expansive and flexible approach" to the obviousness analysis that was grounded in "common sense." *Id.* at 415-16, 421.

The Supreme Court observed that there was an "overemphasis on the importance of published articles and the explicit content of issued patents." *Id.* at 419. The Court emphasized the ability of persons of ordinary skill in the art to use their skill and common sense to reach predictable solutions:

> When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense.

Id. at 421.

Further, while a "patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art," "[t]he

combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *Id.* at 416, 418. In this context, the law presumes that the hypothetical person of ordinary skill in the art is presumed to be aware of ***all*** of the prior art. *Endress + Hauser, Inc. v. Hawk Measurement Sys. Pty. Ltd.*, 122 F.3d 1040, 1042 (Fed. Cir. 1997).

According to *KSR* and the MPEP, "[w]hen considering obviousness of a combination of known elements, ***the operative question is thus 'whether the improvement is more than the predictable use of prior art elements according to their established functions.***'" MPEP § 2141(I) (emphasis added). "If a person of ordinary skill can implement a predictable variation, §103 likely bars its patentability." *KSR*, 550 U.S. at 417. A "person of ordinary skill is also a person of ordinary creativity, not an automaton." *Id.* at 421. Accordingly, "Office personnel may also take into account 'the inferences and creative steps that a person of ordinary skill in the art would employ.'" MPEP § 2141(II) (citing *KSR*). Finally, "if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond that person's skill." *KSR*, 550 U.S. at 417.

The MPEP sets forth the standard for determining obviousness. Once the *Graham* factors are resolved, a determination is made as to whether the claimed invention would have been obvious in light of not just the prior art, but also the understanding of one of ordinary skill in the art. MPEP § 2141(III). "In determining obviousness, neither the particular motivation to make the claimed invention nor the problem the inventor is solving controls. The proper analysis is whether the claimed invention would have been obvious to one of ordinary skill in the art after consideration of all the facts. ***Factors other than the disclosures of the cited prior art may***

provide a basis for concluding that it would have been obvious to one of ordinary skill in the art to bridge the gap. *Id.* (emphasis added). "The Court in *KSR* identified a number of rationales to support a conclusion of obviousness," including the following:

> (A) Combining prior art elements according to known methods to yield predictable results;
>
> (B) Simple substitution of one known element for another to obtain predictable results;
>
> (C) Use of known technique to improve similar devices (methods, or products) in the same way;
>
> (D) Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results;
>
> . . .
>
> (G) Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.

MPEP § 2141(III).

D. REJECTIONS UNDER 35 U.S.C. § 103

1. Overview Of Motivation to Combine Prior Art References

A strong motivation existed to combine the references relied upon by Requester into the combinations set forth herein which form the bases for the proposed rejections. The motivation to combine these references is evidenced by several factors.

First, all of the prior art references relied upon by Requester are in the same specific art area — namely, metal bone plates. Indeed, many of the references relied upon by Requester disclose so-called "hybrid" bone plates — those that having threaded holes and non-threaded holes. These bone plates permit both compression and angular fixation to be achieved in the same bone plate. Other references disclose locking screws that may be used with those plates.

Second, while the prior art references relied upon by Requester disclose a common set of features, characteristics and functions, the various prior art references each disclose additional, and in some cases, unique features, and one of ordinary skill in the art would be motivated to combine a reference showing a particular feature with other references directed to bone plates having similar features and having similar, if not identical, functions.

An example of one such combination is that of the K982222 Summary and the plate described in the Haas Article. Although the K982222 Summary discloses a shaped bone plate having a head and a shaft, threaded holes in its head, and locking screws that have threads "just below" the screw head, it arguably does not discloses locking screw having a "head with a thread." Upon reading the K982222 Summary, one of ordinary skill in the art would be motivated to seek out similar types of plates that use locking screws. One such plate is described in the Haas Article. The Haas Article describes a shaped bone plate having conically-tapered, threaded holes, and locking screws having heads with threads that are used with those holes. Thus, one of ordinary skill in the art, based on the prior art references, would be motivated to combine the disclosure of the locking screws described in the Haas Article with the plate described in the K982222 Summary.

Evidence of the a motivation to combine these references is further shown by the fact that the specific features disclosed in the various references can be easily and predictably applied to the plates shown in other references. For example, like the K982222 Summary, the Zimmer Ad illustrates a shaped bone plate. The Zimmer Ad plate, however, has the additional disclosure of unthreaded suture holes in the head of the plate. There are known advantages to having suture holes present in bone plates to enable surgeons to use sutures (when patient circumstances dictated such use) to assist in securing the plate to the bone. Give the known advantages of

suture holes and the very close similarities between the Zimmer Ad and the K982222 Summary shaped bone plates, one of ordinary skill in the art would be motivated to combine the Zimmer Ad with the K98222 Summary, resulting in a shaped bone plate having all of the features disclosed in the K982222 Summary with the additional feature of suture holes. Further, the suture holes disclosed in the Zimmer Ad, when combined with the bone plate described in the K98222 Summary, will perform in a predictable and similar manner to those in the Zimmer Ad plate. Given the predictable use of such features, the known advantages of such features, and the similarities of the plates shown in the various references, a person of ordinary skill in the art would have been motivated to combine the various references relied upon by Requester into the combinations set forth herein.

Ultimately, the various combinations claimed in the '486 patent do nothing more than substitute or modify the prior art to obtain precisely the results that would be expected by a person of ordinary skill in the art, and, despite any minor differences from the prior art, are obvious. Such minor modifications to the prior art do not rise to the level of invention required to obtain a patent and prevent others from using the well-known features in the prior art for their well-known intended purposes.

These, and other specific examples of motivations to modify or combine the known prior art, can be found below and in the appended claim charts.

2. The Schuhli Guide In View Of Klaue '823

The attached Schuhli Guide in view of Klaue '823 § 103 Claim Chart (Exhibit L) is incorporated by reference herein.

(i) Claims 10-13 are rejected under 35 U.S.C. § 103 as rendered obvious by the Schuhli Guide in view of Klaue '823

As set forth in the chart, one of ordinary skill in the art would be motivated to modify the method disclosed in the Schuhli Guide in view of the integrally formed locking nuts of Klaue '823. The obviousness of the combination is evident not only from the known use of all of these features in virtually an identical manner for osteosynthesis, but also from Klaue '823's specific teaching that devices such as the Schuhli nut can be formed integrally with the plate.

Detailed grounds for rejection are provided in the attached claim chart.

3. Haag In View Of The Schuhli Guide

The attached Haag in view of the Schuhli Guide § 103 Claim Chart (Exhibit M) is incorporated by reference herein.

(i) Claims 10-13 are rejected under 35 U.S.C. § 103 as rendered obvious by Haag in view of The Schuhli Guide

As set forth in the chart, , one of ordinary skill in the art would be motivated to modify the technique for using locking inserts of Haag be used with peri-articular fractures as disclosed in the Schuhli Guide. Haag discloses the use of the invention in buttress plates. Buttress plates may be used to treat peri-articular fractures. For example, the Schuhli Guide discloses a method to treat peri-articular fractures. (*See* p. 2). Using threaded nuts of the kind described in the background of Haag. (*See* Haag at col. 1, l. 65 - col. 2, l. 8). Given Haag's disclosure that it is a substitute for such threaded nuts, one of ordinary skill in the art would appreciate that Haag and the Schuhli Guide can be combined to use the Haag devices to treat peri-articular fractures, as shown in the Schuhli Guide

Detailed grounds for rejection are provided in the attached claim chart.

4. Wolter 117

The attached Wolter 117 § 102 and § 103 Claim Chart (Exhibit H) is incorporated by reference herein.

(i) Claim 11 is rejected under 35 U.S.C. § 103 as rendered obvious by Wolter 117

As set forth in the chart, one of ordinary skill in the art would be motivated to modify the disclosure of Wolter 117 to apply the disclosure to peri-articular fractures. The application of Wolter 117 to such fractures is the result of common sense and would do nothing more than yield predictable results.

Detailed grounds for rejection are provided in the attached claim chart.

5. <u>The Locking Recon Plate Guide In View Of Sutter</u>

The attached Locking Recon Plate Guide in view of Sutter § 103 Claim Chart (Exhibit N) is incorporated by reference herein.

(i) Claims 10 and 13 are rejected under 35 U.S.C. § 103 as rendered obvious by the Locking Recon Plate Guide in view of Sutter

As set forth in the chart, one of ordinary skill in the art would be motivated to modify the surgical technique disclosed in the Locking Recon Plate Guide to use both locking and non-locking screws, as disclosed by Sutter. Sutter discloses that a plate can include alternating holes for locking screws and countersunk holes for compression screws. (*See* col. 7, lines 28-31). Sutter further discloses that both types of screws may be used at the same time. (Col. 7, lines 31-41; Fig. 8). As can be seen in Fig. 8 of Sutter, Sutter discloses a plate similar to the plate used in the Locking Reconstruction Plate Guide. Therefore, in view of Sutter, one of ordinary skill in the art would be appreciate that is a standard 2.4 mm screw is used in step 8, the second fastener inserted in step 9 may be different. It would be obvious to use whatever type of fastener (first or second) is best suited for the location of the plate on the bone.

Detailed grounds for rejection are provided in the attached claim chart.

(ii) Claims 11 and 12 are rejected under 35 U.S.C. § 103(a) as being rendered obvious by the Locking Recon Plate Guide in view of Sutter and in further view of Surer

In addition, one of ordinary skill in the art would b motivated to further modify the method of the Locking Recon Plate Guide and Sutter to peri-articular fractures, as disclosed by Surer. Such an application would be nothing more than one of numerous applications one of ordinary skill would find obvious for the intended use given the known advantages of using such a plate.

Detailed grounds for rejection are provided in the attached claim chart.

6. Kassab

The attached Kassab § 102 and § 103 Claim Chart (Exhibit F) is incorporated by reference herein.

(i) Claim 13 is rejected under 35 U.S.C. § 103 as rendered obvious by Kassab

As set forth in the chart, one of ordinary skill in the art would be motivated to modify the disclosure of Kassab to include a third fastener. Kassab discloses that locking nuts can be used to "create a fixed angle relationship to any screw hole." (p. 91). Therefore, it would be obvious to insert a third fastener at a fixed angular relationship to the bone plate, using a nut, with a different angular relationship than the second fastener. Including a third fastener is the result of common sense and would do nothing more than yield predictable results.

Detailed grounds for rejection are provided in the attached claim chart.

7. Kassab In View Of The Haas Article And Klaue '823

The attached Kassab in view of the Haas Article and Klaue '823 § 103 Claim Chart (Exhibit O) is incorporated by reference herein.

(i) Claims 1, 6, and 7 are rejected under 35 U.S.C. § 103(a) as rendered obvious by Kassab in view of Haas and in further view of Klaue '823

As set forth in the chart, one of ordinary skill in the art would be motivated to modify the locking nut procedures of Kassab with the threaded holes of the Haas Article and the integrally formed locking nuts of Klaue '823. It would have been obvious to combine Kassab with Klaue '823 to form the Schuhli nut integrally with the plate, and with Haas to provide a locking bone plate screw having a head with a thread. The obviousness of the combination is evident not only from the known use of all of these features in virtually an identical manner for osteosynthesis, but also from Klaue '823's specific teaching that devices such as the Schuhli nut can be formed integrally with the plate, and the Haas Article's teaching of a substitute bone plate screw having a threaded head.

(ii) Claims 2, 3, 5, and 9 are rejected under 35 U.S.C. § 103(a) as rendered obvious by Kassab in view of Haas and in further view of the Admitted Prior Art in the '486 Patent

As set forth in the chart, one of ordinary skill in the art would be further motivated to modify the combination in view of the Admitted Prior Art of the '486 patent. Indeed, one of ordinary skill in the art was well-aware of different types of screws, including self-tapping screws. These types of screws are nothing more than one of numerous existing screw types one of ordinary skill would find obvious for the intended use given the known advantages of using such screws.

Detailed grounds for rejection are provided in the attached claim chart.

(iii) Claim 4 is rejected under 35 U.S.C. § 103(a) as rendered obvious by Kassab in view of Haas and in further view of Decoste

As set forth in the chart, one of ordinary skill in the art would be motivated to further modify this combination in view of the cannulated screw disclosed in Decoste. Like Kassab and the Haas Article, Decoste discloses devices for use in orthopedic bone surgery. One of ordinary

skill in the art using guide wires to aid in accurate screw placement would be motivated to look to cannulated screws based on the advantages of doing of such screws.

Detailed grounds for rejection are provided in the attached claim chart.

(iv) Claims 8 and 18 are rejected under 35 U.S.C. § 103(a) as rendered obvious by Kassab in view of Haas and in further view of the Manual of Internal Fixation

As set forth in the chart, one of ordinary skill in the art would be motivated to further modify this combination in view of the trapezoidal cross section disclosed in the Manual of Internal Fixation. Like Kassab and the Haas Article, the Manual of Internal Fixation discloses devices for use in orthopedic bone surgery. Specifically, Kassab discloses the use of Schuhli Nuts as locking devices with a DCP plate. As described above, the Schuhli Technique Guide discloses that the Schuhli's may be used with a DCP or a LC-DCP plate, as is disclosed in the Manual of Internal Fixation. One of ordinary skill in the art would understand that such an LC-DCP plate has a trapezoidal cross section as disclosed in the Schuhli Guide and could be used in place of a DCP plate given the advantages as described in the Manual of Internal Fixation. *See, e.g.*, p. 241; Fig. 3.40A.

Detailed grounds for rejection are provided in the attached claim chart.

(v) Claims 14 and 15 are rejected under 35 U.S.C. § 103(a) as rendered obvious by Kassab in view of Haas and in further view of Chapman

As set forth in the chart, one of ordinary skill in the art would be further motivated to modify the combination in view of the flared head portion disclosed in Chapman. One of ordinary skill in the art seeking to improve the fit between the bone plate and bone would refer to shaped bone plates, such as that disclosed in Chapman, and would be motivated to further modify the plate to have a head portion that flares out. Accordingly, it would have been obvious to one of ordinary skill in the art to modify the combination of Kassab and the Haas Article to

achieve the known and predictable benefits of providing a better fit to the bone.

Detailed grounds for rejection are provided in the attached claim chart.

(vi) Claim 16 is rejected under 35 U.S.C. § 103(a) as rendered obvious by Kassab in view of Haas and in further view of the Synthes Catalog

As set forth in the chart, one of ordinary skill in the art would be motivated to further modify this combination in view of the forked head of Condylar Buttress Plate disclosed in the Synthes Catalog given that the Condylar Buttress Plate is one of the plates in which Schuhli Nuts as disclosed in Kassab may be used with.

Detailed grounds for rejection are provided in the attached claim chart.

(vii) Claim 17 is rejected under 35 U.S.C. § 103(a) as rendered obvious by Kassab in view of Haas

As described above, one of ordinary skill in the art would be motivated to further modify this combination in view of threaded holes disclosed in Haas.

Detailed grounds for rejection are provided in the attached claim chart.

8. <u>Mückter In View Of The Haas Article</u>

The attached Mückter in view of the Haas Article § 103 Claim Chart (Exhibit P) is incorporated by reference herein.

(i) Claims 1, 4, 6, 7, 9, 14, 15, and 17 are rejected under 35 U.S.C. § 103(a) as rendered obvious by Mückter in view of Haas

As set forth in the chart, one of ordinary skill in the art would be motivated to combine the Mückter's shaped bone plate with the conically-tapered and threaded holes and screws having heads with threads disclosed in the Haas Article. Mückter and the Haas Article both describe peri-articular bone plates having locking holes for insertion into the bone condyle, and both plates are used for similar conditions. As such, it would be obvious to use features from one plate in the other to obtain their known benefits.

Detailed grounds for rejection are provided in the attached claim chart.

(ii) Claims 2, 3, and 5 are rejected under 35 U.S.C. § 103(a) as rendered obvious by Mückter in view of Haas and in further view of Stednitz

As set forth in the chart, one of ordinary skill in the art would be motivated to further modify the combination with self-tapping and self-drilling screws disclosed in Stednitz. Like Mückter and of Haas, Stednitz discloses an orthopedic implant. Stednitz discloses "[a] self-tapping, self-drilling orthopedic fixation screw." Abstract. It would be obvious to modify the screw of Mückter to be self-tapping given the advantages of using such a screw. "[T]he cutting edges 36 of the threaded portions 30 being to tap threads into the bone 40. Further rotation of the shaft 12 with application of sufficient force between the shaft 12 and bone 40 results in simultaneous drilling and tapping of the passage 42 in the bone 40." (Col. 3, lines 61-66).

Detailed grounds for rejection are provided in the attached claim chart.

(iii) Claims 8 and 18 are rejected under 35 U.S.C. § 103(a) as rendered obvious by Mückter in view of Haas and in further view of Klaue '544

As set forth in the chart, one of ordinary skill in the art would be further motivated to modify the combination in view of the trapezoidal shaped cross section disclosed in Klaue '544. Like Mückter and the Haas Article, Klaue '544 discloses a bone plate. One of ordinary skill in the art seeking to reduce contact between the bone plate and the bone would refer to straight bone plates having limited contact features, such as Klaue '544's trapezoidal shaped cross section. Klaue '544 discloses that such a structure "minim[izes] bone contact, which in turn promotes vascularization and bone growth." Klaue '544, Col. 3, lines 46-48. Accordingly, it would have been obvious to one of ordinary skill in the art to modify the combination of Mückter and the Haas Article to achieve the known and predictable benefits of promoting vascularization and bone growth.

Detailed grounds for rejection are provided in the attached claim chart.

9. Mückter In View Of Wolter 117

The attached Mückter in view of Wolter 117 § 103 Claim Chart (Exhibit Q) is incorporated by reference herein.

(i) Claims 1, 4, 6, 7, 9, 14, 15, and 17 are rejected under 35 U.S.C. § 103(a) as rendered obvious by Mückter in view of Wolter 117

As set forth in the chart, one of ordinary skill in the art would be motivated to combine the Mückter's shaped bone plate with the conically-tapered and threaded holes and screws having heads with threads disclosed in Wolter 117. Wolter 117 teaches that it is a useful substitute for bone plates having various types of locking screw, including plates having "the screw head with an outer thread and the plate hole with an inner thread." *Id.*, col. 1, sixth paragraph. Thus, Wolter 117 provides an explicit motivation to combine its teachings with other references using threaded locking screws. Furthermore, Wolter 117 specifically discloses the interchangeability of a screw having a thread just below an enlarged "head" portion and screws having the threads on the head itself. This interchangeability is shown, for example, in Figure 2 of Wolter 117, which discloses an alternative locking screw having "a stop 12 projecting to the side ... to prevent the screw 1 from reaching through the passage hole of plate 8." *Id.* at col. 4, fourth paragraph. Given this teaching, it would have been obvious to the person of ordinary skill in the art to replace Mückter's locking screw with a locking screw having a "head with a thread." It also would have been obvious to incorporate the conical and multiple-lead thread features in Wolter 117 to improve the construction of the locking screw/plate interface refer to other bone plates having threaded holes and locking screws, and would be motivated to implement their known features.

Detailed grounds for rejection are provided in the attached claim chart.

(ii) Claims 2, 3, and 5 are rejected under 35 U.S.C. § 103(a) as rendered obvious by Mückter in view of Haas and in further view of Stednitz

As described above, one of ordinary skill in the art would be motivated to further modify this combination to include the screw features disclosed in Stednitz.

Detailed grounds for rejection are provided in the attached claim chart.

(iii) Claims 8 and 18 are rejected under 35 U.S.C. § 103(a) as rendered obvious by Mückter in view of Wolter 117 and in further view of Klaue '544

As described above, one of ordinary skill in the art would be motivated to further modify this combination to include the trapezoidal shaped cross section disclosed in Klaue '544.

Detailed grounds for rejection are provided in the attached claim chart.

10. <u>Mückter In View Of The Synthes Catalog</u>

The attached Mückter in view of the Synthes Catalog § 103 Claim Chart (Exhibit R) is incorporated by reference herein. This chart also incorporates § 102 rejections using Mückter as described above.

(i) Claims 2, 3, and 5 are rejected under 35 U.S.C. § 103(a) as rendered obvious by Mückter in view of Admitted Prior Art in the '486 Patent

As described above, one of ordinary skill in the art would be motivated to further modify this combination to include the screw features disclosed in the '486 patent as admitted prior art.

Detailed grounds for rejection are provided in the attached claim chart.

(ii) Claims 6, 7, and 17 are rejected under 35 U.S.C. § 103(a) as rendered obvious by Mückter in view of Haas

As described above, one of ordinary skill in the art would be motivated to further modify this combination to include the threaded holes disclosed in Haas.

Detailed grounds for rejection are provided in the attached claim chart.

(iii) Claims 8, 16, and 18 are rejected under 35 U.S.C. § 103(a) as rendered obvious by Mückter in view the Synthes Catalog

As set forth in the chart, one of ordinary skill in the art would be motivated to combine the Mückter's shaped bone plate with the condylar buttress plate disclosed in the Synthes Catalog. Both Mückter and the Synthes Catalog describe plates for treatment of peri-articular fractures. It was well-known to use bone plates having various different shapes and to provide limited contact profiles on the lower surface of condylar buttress plates, as shown by the Synthes Catalog.

Detailed grounds for rejection are provided in the attached claim chart.

11. The K982222 Summary

The attached K982222 Summary § 103 Claim Chart (Exhibit S) is incorporated by reference herein.

(i) Claims 1-9 and 14-18 are rejected under 35 U.S.C. § 103 as rendered obvious by the K982222 Summary

As set forth in the chart, based on the disclosure of the K982222 Summary, one of ordinary skill would be motivated to use screws having a thread with a head with the bone plate described in the K982222 Summary. Such screws are nothing more than one of numerous configurations one of ordinary skill would find obvious for the intended use given the known advantages of using such a screw. Further, placing the threads onto the head of the screw is known in the art, and would yield the predictable result of allowing the head of the screw to sit flush with or below the upper surface of the bone plate.

Detailed grounds for rejection are provided in the attached claim chart.

12. The K982222 Summary In View Of Bolhofner

The attached K982222 in view of Bolhofner § 103 Claim Chart (Exhibit T) is incorporated by reference herein.

(i) Claims 1-9 and 17 are rejected under 35 U.S.C. § 103(a) as rendered obvious by K982222 in view of Bolhofner

As set forth in the chart, one of ordinary skill in the art would be motivated to modify the shaped plate described in the K982222 Summary to have "selective locking" as disclosed in Bolhofner. Bolhofner discloses that using shaped bone plates, like the plate described in the K982222 Summary, one can provide a locked screw wherever it is necessary to address screw angulation, which can happen anywhere on the bone plate. Thus, it would have been a simple matter of design choice to use all locking screw holes in the plate head or to locking screw holes in the shaft, depending on the underlying bone condition, to address and prevent screw angulation.

Detailed grounds for rejection are provided in the attached claim chart.

13. The K982222 Summary In View Of The Haas Article

The attached K982222 in view of the Haas Article § 103 Claim Chart (Exhibit U) is incorporated by reference herein.

(i) Claims 1, 2, 3, 4, 6, 7, 14, 16, and 17 are rejected under 35 U.S.C. § 103(a) as rendered obvious by K982222 in view of Haas

As set forth in the chart, one of ordinary skill in the art would be motivated to combine the shaped plate described in the K982222 Summary to with the screws having a threaded head disclosed in the Haas Article. Like the K982222 Summary, the Haas Article discloses a shaped bone plate having a head portion and a shaft portion, and both are for use with the distal femur and use locking screws. One of ordinary skill in the art would have been motivated to include only threaded locking bone anchor holes in the plate head, because the Haas Article illustrates

the desirability of such an arrangement in a distal femur plate to treat distal femur fractures. Further, one would have been motivated to replace the K982222 Summary's locking screws having a thread just below the head with locking screws as shown in the Haas Article having threads that surround the head. The interchangeability of these two designs is apparent to a person of ordinary skill in the art because there are only a limited number of discrete designs for threaded locking bone plate screws, and it would be an obvious matter to put the threads either around or "just below" or on the bottom surface of the head. One would also have been motivated to use a conical threaded hole and double-lead thread, as these features are, once again, selected from a limited number of discrete designs for threaded bone plate screw holes, and thus an obvious design choice. Moreover, one would have been motivated to include the suture holes in the head of the LISS plate in the Haas Article to the DFP plate described in K982222 to obtain their known benefits.

Detailed grounds for rejection are provided in the attached claim chart.

(ii) Claims 5 and 9 are rejected under 35 U.S.C. § 103(a) as rendered obvious by K982222 in view of Haas and in further view of the Admitted Prior Art in the '486 Patent

As set forth in the chart, one of ordinary skill in the art would be further motivated to modify the combination in view of the Admitted Prior Art of the '486 patent. Indeed, one of ordinary skill in the art was well-aware of different types of screws, including self-tapping screws. These types of screws are nothing more than one of numerous existing screw types one of ordinary skill would find obvious for the intended use given the known advantages of using such screws.

Further, one of ordinary skill in the art was well-aware of screw holes that were longitudinally elongated and had an inclined edge given the known advantages of using such holes.

Detailed grounds for rejection are provided in the attached claim chart.

(iii) Claims 8 and 18 are rejected under 35 U.S.C. § 103(a) as rendered obvious by K982222 in view of Haas and in further view of Klaue '544

As set forth in the chart, one of ordinary skill in the art would be motivated to combine the K982222 Summary's condylar buttress plate with a shaft having a limited contact profile with the trapezoidal-shaped cross section in the plate shown in Klaue '544. Klaue '544 discloses a straight bone plate having low contact features. Even though Klaue '544 discloses a straight bone plate, such plates are generally positioned over the same part of the bone — the diaphysis — that the shaft portion of the shaped bone plates are positioned, and can even be thought of as shaped bone plates without head portions. Based on these similarities, one of ordinary skill in the art would be motivated to look to these straight plates, and their low-contact features, and implement those features in the straight shaft portions of the shaped bone plates. Including a trapezoidal-shaped cross section in the shaft portion of the K982222 Summary's condylar buttress plate would achieve the known, predictable solution of "minimiz[ing] bone contact, which in turn promotes vascularization and bone growth." Klaue '544, Col. 3, lines 46-48.

Detailed grounds for rejection are provided in the attached claim chart.

(iv) Claim 15 is rejected under 35 U.S.C. § 103(a) as rendered obvious by K982222 in view of Haas and in further view of the Zimmer Ad

Like the K982222 Summary and the Haas Article, the Zimmer Ad describes a bone plate having a head portion and a shaft portion, and with similar application to the bone. Based on this, one of ordinary skill in the art would be motivated to modify the combination of the K982222 Summary and the Haas Article with the known suture holes, disclosed in the Zimmer Ad to achieve the predictable solution of enabling the plate to be used with sutures.

Detailed grounds for rejection are provided in the attached claim chart.

14. The K982222 Summary In View Of The Collin Catalog

The attached K982222 in view of the Collin Catalog § 103 Claim Chart (Exhibit V) is incorporated by reference herein.

(i) Claims 1, 2, 3, 4, 6, 14, 16, and 17 are rejected under 35 U.S.C. § 103(a) as rendered obvious by K982222 in view of the Collin Catalog

As set forth in the chart, one of ordinary skill in the art would be motivated to combine the K982222 Summary's shaped bone plate with the conically-tapered and threaded holes disclosed in the Collin Catalog. The Collin Catalog describes bone plates, including shaped bone plates having head portions and shaft portions, and straight bone plates having it conically-tapered and threaded holes.[18] Because of this, one would be motivated to incorporate these threaded, conically tapered holes with screws having threaded heads to achieve the known, predictable solution of using threaded, conically tapered holes with locked screws to reduce the profile of the screw/plate combination and to achieve an angularly stable screw/plate connection both in the head portion and in the shaft portion of the shaped bone plate.

Detailed grounds for rejection are provided in the attached claim chart.

(ii) Claims 5 and 9 are rejected under 35 U.S.C. § 103(a) as rendered obvious by K982222 in view of the Collin Catalog and in further view of the Admitted Prior Art in the '486 Patent

As described above, one of ordinary skill in the art would be motivated to further modify this combination in view of the Admitted Prior Art in the '486 patent.

Detailed grounds for rejection are provided in the attached claim chart.

---

[18] *See Boston Scientific SciMed, Inc. v. Cordis Corp.*, 554 F.3d 982, 991 (Fed. Cir. 2009) ("Combining two embodiments disclosed adjacent to each other in a prior art patent does not require a leap of inventiveness").

(iii) Claim 7 is rejected under 35 U.S.C. § 103(a) as rendered obvious by K982222 in view of the Collin Catalog and in further view of Trebing

Trebing discloses a bone plate having screws with multiple lead threads. One seeking to improve the construction of the locking screw/plate interface refer to other bone plates having threaded holes and locking screws, and would be motivated to implement their known features.

Detailed grounds for rejection are provided in the attached claim chart.

(iv) Claims 8 and 18 are rejected under 35 U.S.C. § 103(a) as rendered obvious by K982222 in view of the Collin Catalog and in further view of Klaue '544

As described above, one of ordinary skill in the art would be motivated to further modify this combination to include the trapezoidal shaped cross section disclosed in Klaue '544.

Detailed grounds for rejection are provided in the attached claim chart.

(v) Claim 15 is rejected under 35 U.S.C. § 103(a) as rendered obvious by K982222 in view of the Collin Catalog and in further view of the Zimmer Ad

As described above, one of ordinary skill in the art would be motivated to further modify this combination to include the suture holes disclosed in the Zimmer Ad.

Detailed grounds for rejection are provided in the attached claim chart.

15. <u>The K982222 Summary In View Of Wolter 117</u>

The attached K982222 in view of Wolter 117 § 103 Claim Chart (Exhibit W) is incorporated by reference herein.

(i) Claims 1, 2, 3, 4, 6, 7, 14, 16, and 17 are rejected under 35 U.S.C. § 103(a) as rendered obvious by K982222 in view of Wolter 117

As set forth in the chart, one of ordinary skill in the art would be motivated to combine the K982222 Summary's shaped bone plate with the conically-tapered and threaded holes and screws having heads with threads disclosed in Wolter 117. Wolter 117 discloses that it is a

useful substitute for bone plates having various types of locking screw, including plates having "the screw head with an outer thread and the plate hole with an inner thread." *Id.*, col. 1, sixth paragraph. Thus, Wolter 117 provides and explicit motivation to combine its teachings with other references using threaded-head locking screws. Furthermore, Wolter 117 specifically discloses the interchangeability of a screw having a thread just below an enlarged "head" portion and screws having the threads on the head itself. This interchangeability is shown, for example, in Figure 2 of Wolter 117, which discloses an alternative locking screw having "a stop 12 projecting to the side ... to prevent the screw 1 from reaching through the passage hole of plate 8." *Id.* at col. 4, fourth paragraph. Given this teaching, one of ordinary skill in the art would have been motivated to replace the K982222 Summary's locking screw having "threads just below the head" with a locking screw having a "head with a thread, " and to incorporate the conical and multiple-lead thread features in Wolter 117.

Detailed grounds for rejection are provided in the attached claim chart.

(ii) Claims 5 and 9 are rejected under 35 U.S.C. § 103(a) as rendered obvious by K982222 in view of Wolter 117 and in further view of the Admitted Prior Art in the '486 Patent

As described above, one of ordinary skill in the art would be motivated to further modify this combination in view of the Admitted Prior Art in the '486 patent.

Detailed grounds for rejection are provided in the attached claim chart.

(iii) Claims 8 and 18 are rejected under 35 U.S.C. § 103(a) as rendered obvious by K982222 in view of Wolter 117 and in further view of Klaue '544

As described above, one of ordinary skill in the art would be motivated to further modify this combination to include the trapezoidal shaped cross section disclosed in Klaue '544.

Detailed grounds for rejection are provided in the attached claim chart.

(iv) Claim 15 is rejected under 35 U.S.C. § 103(a) as rendered obvious by K982222 in view of Wolter 117 and in further view of the Zimmer Ad

As described above, one of ordinary skill in the art would be motivated to further modify this combination in view of suture holes disclosed in the Zimmer Ad.

Detailed grounds for rejection are provided in the attached claim chart.

16. The K982222 Summary In View Of Wolter 117 And Bolhofner

The attached K982222 in view of Wolter 117 and Bolhofner § 103 Claim Chart (Exhibit X) is incorporated by reference herein.

(i) Claims 1, 2, 3, 4, 6, 7, 14, 16, and 17 are rejected under 35 U.S.C. § 103(a) as rendered obvious by K982222 in view of Wolter 117 and in further view of Bolhofner

As described above, one of ordinary skill in the art would be motivated to combine the K982222 Summary's shaped bone plate with the conically-tapered and threaded holes and screws having heads with threads disclosed in Wolter 117 and the selective locking of Bolhofner.

Detailed grounds for rejection are provided in the attached claim chart.

(ii) Claims 5 and 9 are rejected under 35 U.S.C. § 103(a) as rendered obvious by K982222 in view of Wolter 117 and Bolhofner and in further view of the Admitted Prior Art in the '486 Patent

As described above, one of ordinary skill in the art would be motivated to further modify this combination in view of the Admitted Prior Art in the '486 patent.

Detailed grounds for rejection are provided in the attached claim chart.

(iii) Claims 8 and 18 are rejected under 35 U.S.C. § 103(a) as rendered obvious by K982222 in view of Wolter 117 and Bolhofner and in further view of Klaue '544

As described above, one of ordinary skill in the art would be motivated to further modify this combination to include the trapezoidal shaped cross section disclosed in Klaue '544.

Detailed grounds for rejection are provided in the attached claim chart.

(iv) Claim 15 is rejected under 35 U.S.C. § 103(a) as rendered obvious by K982222 in view of Wolter 117 and Bolhofner and in further view of the Zimmer Ad

As described above, one of ordinary skill in the art would be motivated to further modify this combination in view of suture holes disclosed in the Zimmer Ad.

Detailed grounds for rejection are provided in the attached claim chart.

(v) Claim 16 is rejected under 35 U.S.C. § 103(a) as rendered obvious by K982222 in view of Wolter 117

As described above, one of ordinary skill in the art would be motivated to further modify this combination in view of locking screws disclosed in Wolter 117.

Detailed grounds for rejection are provided in the attached claim chart.

17. <u>The K982222 Summary In View Of The Synthes Catalog</u>

The attached K982222 in view of the Synthes Catalog § 103 Claim Chart (Exhibit Y) is incorporated by reference herein. Claim 1 is rejected as shown in Exhibit S under K982222.

(i) Claims 8, 16, and 18 are rejected under 35 U.S.C. § 103(a) as rendered obvious by K982222 in view the Synthes Catalog

As set forth in the chart, one of ordinary skill in the art be motivated to combine the condylar buttress plate disclosed in the K982222 Summary with the condylar buttress plate shown in the Synthes Catalog. Indeed, the condylar buttress plate is identified as a "predicate device" for the system described in the K982222 Summary. Upon reading the K982222 Summary, one of ordinary skill in the art would be motivated to seek out similar types of shaped bone plates, including the LC-DCP condylar buttress plate.

Detailed grounds for rejection are provided in the attached claim chart.

18. <u>The Schuhli Guide In View Of The Haas Article</u>

The attached Schuhli Guide in view of the Haas Article § 103 Claim Chart (Exhibit Z) is incorporated by reference herein.

(i) Claims 1, 5, 6, 7, and 17 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the Schuhli Guide in view of Haas

As set forth in the chart, one of ordinary skill in the art would be motivated to modify the bone plate disclosed in the Schuhli Guide with the teachings of the Haas Article. The Haas Article describes a "LISS" bone plate having conical, dual-threaded locking holes, and corresponding threaded-head locking screws. *See, e.g.*, Haas Article Fig. 3. Just like in the Schuhli Guide, the locking screw in the Haas Article are used to secure bone at a fixed angular relationship. In addition, the Haas Article and the Schuhli Guide both disclose the bone plate and screw system being used to secure condylar fractures in the long bones, such as the femur. Given the similarity of these teachings and their virtually identical uses, it would have been obvious to a person of ordinary skill in the art to either (i) modify the Schuhli Washers shown in the Schuhli Guide to include the conical, dual-threaded locking holes of the Haas Article to obtain benefits of such fasteners, or (ii) modify the plate holes themselves to have the conical, dual-threaded locking features in the Haas Article.

Detailed grounds for rejection are provided in the attached claim chart.

(ii) Claims 2, 3, and 9 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the Schuhli Guide in view of Haas and in further view of the Admitted Prior Art in the '486 Patent

As set forth in the chart, one of ordinary skill in the art would be further motivated to modify the combination in view of the Admitted Prior Art of the '486 patent. Indeed, one of ordinary skill in the art was well-aware of different types of screws, including self-tapping screws and self-drilling screws. These types of screws are nothing more than one of numerous existing screw types one of ordinary skill would find obvious for the intended use given the known advantages of using such screws.

Further, one of ordinary skill in the art was well-aware of screw holes that were longitudinally elongated and had an inclined edge given the known advantages of using such holes.

Detailed grounds for rejection are provided in the attached claim chart.

(iii) Claim 4 is rejected under 35 U.S.C. § 103(a) as rendered obvious by the Schuhli Guide in view of Haas and in further view of Decoste

As set forth in the chart, one of ordinary skill in the art would be further motivated to modify the combination in view of the cannulated screws disclosed in Decoste. Like the Schuhli Guide and the Haas Article, Decoste discloses devices for use in orthopedic bone surgery. Further, the Schuhli Guide discloses the use of K-wires. One of ordinary skill in the art using such K-wires as guide wires to aid in accurate screw placement would be motivated to look to cannulated screws based on the advantages of doing of such screws.

Detailed grounds for rejection are provided in the attached claim chart.

(iv) Claims 8 and 18 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the Schuhli Guide in view of Haas and in further view of the Manual of Internal Fixation

As set forth in the chart, one of ordinary skill in the art would be further motivated to modify the combination in view of the bone plate of the Manual of Internal Fixation having a trapezoidal cross section. Indeed, the Schuhli Guide expressly states that Schuhlis can be used with a LC-DCP, such as those disclosed in the Manual of Internal Fixation. The Manual of Internal Fixation discloses that the LC-DCP has a trapezoidal cross section. *See* pp. 241, 243; Fig. 3.40A. Accordingly, it would have been obvious to one of ordinary skill in the art that the Schuhli Guide plate has a trapezoidal cross section.

Detailed grounds for rejection are provided in the attached claim chart.

(v) Claims 14 and 15 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the Schuhli Guide in view of Haas and in further view of Chapman

As set forth in the chart, one of ordinary skill in the art would be further motivated to modify the combination in view of the flared head portion disclosed in Chapman. One of ordinary skill in the art seeking to improve the fit between the bone plate and bone would refer to shaped bone plates, such as that disclosed in Chapman, and would be motivated to further modify the plate to have a head portion that flares out. Accordingly, it would have been obvious to one of ordinary skill in the art to modify the combination of the Schuhli Guide and the Haas Article to achieve the known and predictable benefits of providing a better fit to the bone.

Detailed grounds for rejection are provided in the attached claim chart.

(vi) Claim 16 is rejected under 35 U.S.C. § 103(a) as rendered obvious by the Schuhli Guide in view of Haas and in further view of the Synthes Catalog

As set forth in the chart, one of ordinary skill in the art would be further motivated to modify the combination in view of the forked head disclosed in the Synthes Catalog. One of ordinary skill in the art seeking to improve the fit between the bone plate and bone would refer to shaped bone plates, such as that disclosed in the Synthes Catalog, and would be motivated to further modify the plate to have a head portion that flares out. Accordingly, it would have been obvious to one of ordinary skill in the art to modify the combination of the Schuhli Guide and the Haas Article to achieve the known and predictable benefits of providing a better fit to the bone.

Detailed grounds for rejection are provided in the attached claim chart.

19. <u>The Schuhli Guide In View Of The Haas Article And Klaue '823</u>

The attached Schuhli Guide in view of Haas and Klaue '823 § 103 Claim Chart (Exhibit AA) is incorporated by reference herein.

(i) Claims 1, 5, 6, 7, and 17 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the Schuhli Guide in view of Haas and in further view of Klaue '823

As set forth in the chart and described above, one of ordinary skill in the art would be motivated to modify the bone plate disclosed in the Schuhli Guide with the teachings of the Haas Article. One of ordinary skill in the art would be further motivated to modify the bone plate disclosed in the Schuhli Guide with the teachings of Klaue '823. Klaue '823 teaches that separate locking washers such as those in the Schuhli Guide can be formed integrally with the plate. *See,* Klaue '823 at col. 5, ll. 18-40 and Figs. 8-9. The Schuhli Guide teaches that a locking screw can be placed wherever desired, including the plate head and the plate shaft. *See, supra.* Given these teachings, a person of ordinary skill in the art would have found it obvious to reconfigure the patterns of locking washers shown in the Schuhli Guide in any fashion to address the particular bone conditions, and would have found it obvious to make the Schuhli Washers integral with the plate. For example, it would have been obvious to make all of the holes through the head of the plate with integrally formed threaded holes (claim 1) and it would have been obvious to the use both threaded and unthreaded holes through the plate shaft (claim 17). Given the teachings in the Haas Article, it also would have been obvious to use locking screws having heads with threads to mate with these threaded holes, and to make the threaded holes with the shape shown in the Haas Article. As such, the various patterns of screws and other known features recited in the '486 patent claims, are suggested by this obvious combination.

Detailed grounds for rejection are provided in the attached claim chart.

(ii) Claims 2, 3, and 9 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the Schuhli Guide in view of Haas and Klaue '823 and in further view of the Admitted Prior Art in the '486 Patent

As described above, one of ordinary skill in the art would be motivated to further modify this combination in view of the Admitted Prior Art in the '486 patent.

Detailed grounds for rejection are provided in the attached claim chart.

(iii) Claim 4 is rejected under 35 U.S.C. § 103(a) as rendered obvious by the Schuhli Guide in view of Haas and Klaue '823 and in further view of Decoste

As described above, one of ordinary skill in the art would be motivated to further modify this combination in view of Decoste.

Detailed grounds for rejection are provided in the attached claim chart.

(iv) Claims 8 and 18 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the Schuhli Guide in view of Haas and Klaue '823 and in further view of the Manual of Internal Fixation

As described above, one of ordinary skill in the art would be motivated to further modify this combination in view of the Manual of Internal Fixation.

Detailed grounds for rejection are provided in the attached claim chart.

(v) Claims 14 and 15 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the Schuhli Guide in view of Haas and in further view of Chapman

As set forth in the chart, one of ordinary skill in the art would be further motivated to modify the combination in view of the flared head portion disclosed in Chapman. One of ordinary skill in the art seeking to improve the fit between the bone plate and bone would refer to shaped bone plates, such as that disclosed in Chapman, and would be motivated to further modify the plate to have a head portion that flares out. Accordingly, it would have been obvious to one of ordinary skill in the art to modify the combination of the Schuhli Guide and the Haas Article to achieve the known and predictable benefits of providing a better fit to the bone.

Detailed grounds for rejection are provided in the attached claim chart.

(vi) Claim 16 is rejected under 35 U.S.C. § 103(a) as rendered obvious by the Schuhli Guide in view of Haas and in further view of the Synthes Catalog

As set forth in the chart, one of ordinary skill in the art would be further motivated to modify the combination in view of the forked head disclosed in the Synthes Catalog. One of ordinary skill in the art seeking to improve the fit between the bone plate and bone would refer to shaped bone plates, such as that disclosed in the Synthes Catalog, and would be motivated to further modify the plate to have a head portion that flares out. Accordingly, it would have been obvious to one of ordinary skill in the art to modify the combination of the Schuhli Guide and the Haas Article to achieve the known and predictable benefits of providing a better fit to the bone.

Detailed grounds for rejection are provided in the attached claim chart.

20. <u>The Schuhli Guide In View Of Wolter 117 And Klaue '823</u>

The attached Schuhli Guide in view of Wolter 117 and Klaue '823 § 103 Claim Chart (Exhibit BB) is incorporated by reference herein.

(i) Claims 1, 5, 6, 7, and 17 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the Schuhli Guide in view of Wolter 117 and in further view of Klaue '823

As set forth in the chart, one of ordinary skill in the art would be motivated to modify the plate described in the Schuhli Guide with the screw having a head with a thread disclosed in Wolter 117. Wolter 117 teaches a locking bone screw system that is a that it is a useful substitute for other kinds of locking bone plate screws. *See* Wolter 117, col. 1. Thus, Wolter 117 provides and explicit motivation to combine its teachings with other references using locking screws. Furthermore, Wolter 117 specifically discloses the interchangeability of a screw having a thread just below an enlarged "head" portion and screws having the threads on the head itself. *See, e.g., id.* Fig. 2 (alternative locking screw having head-like projection) *and* col. 4, fourth paragraph (describing same). Given this teaching, it would have been obvious to the

person of ordinary skill in the art to replace the locking screw arrangement in the Schuhli Guide with locking screws having "head with a thread" (independent claims), conical threaded holes (claim 6), and multiple-lead threads (claim 7), as shown in Wolter 117.

Further, as set forth in the chart and described above, one of ordinary skill in the art would be motivated to modify the bone plate disclosed in the Schuhli Guide with Klaue '823.

Detailed grounds for rejection are provided in the attached claim chart.

(ii) Claims 2, 3, and 9 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the Schuhli Guide in view of Wolter 117 and Klaue '823 and in further view of the Admitted Prior Art in the '486 Patent

As described above, one of ordinary skill in the art would be motivated to further modify this combination in view of the Admitted Prior Art in the '486 patent.

Detailed grounds for rejection are provided in the attached claim chart.

~~(iii) Claim 4 is rejected under 35 U.S.C. § 103(a) as rendered obvious by the Schuhli Guide in view of Wolter 117 and Klaue '823 and in further view of Decoste~~

As described above, one of ordinary skill in the art would be motivated to further modify this combination in view of Decoste.

Detailed grounds for rejection are provided in the attached claim chart.

(iv) Claims 8 and 18 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the Schuhli Guide in view of Wolter 117 and Klaue '823 and in further view of the Manual of Internal Fixation

As described above, one of ordinary skill in the art would be motivated to further modify this combination in view of the Manual of Internal Fixation.

Detailed grounds for rejection are provided in the attached claim chart.

(v) Claim 14 is rejected under 35 U.S.C. § 103(a) as rendered obvious by the Schuhli Guide in view of Wolter 117 and in further view of Chapman

As described above, one of ordinary skill in the art would be motivated to further modify this combination in view of Chapman.

Detailed grounds for rejection are provided in the attached claim chart.

(vi) Claim 15 is rejected under 35 U.S.C. § 103(a) as rendered obvious by the Schuhli Guide in view of Wolter 117 and Chapman and in further view of the Zimmer Ad

The Zimmer Ad describes a bone plate used to treat similar fractures on the bone. Based on this, one of ordinary skill in the art would be further motivated to modify the combination with the known provisional fixation holes, *i.e.*, unthreaded suture holes, disclosed in the Zimmer Ad to achieve the predictable solution of enabling the plate to be used with sutures.

Detailed grounds for rejection are provided in the attached claim chart.

(vii) Claim 16 is rejected under 35 U.S.C. § 103(a) as rendered obvious by the Schuhli Guide in view of Wolter 117 and in further view of the Synthes Catalog

As described above, one of ordinary skill in the art would be motivated to further modify this combination in view of the Synthes Catalog.

Detailed grounds for rejection are provided in the attached claim chart.

21. <u>The Zimmer Ad In View Of The Haas Article</u>

The attached Zimmer Ad in view of the Haas Article § 103 Claim Chart (Exhibit CC) is incorporated by reference herein.

(i) Claims 1, 6, 7, 9, 14, 15, and 17 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the Zimmer Ad in view of Haas

As set forth in the chart, one of ordinary skill in the art would be motivated to combine the Zimmer Ad's shaped bone plate with the conically-tapered and threaded holes and screws having heads with threads disclosed in the Haas Article. Both references describe similar bone plates for long bone fractures, and the Haas Article demonstrates the desirability of using

threaded locking screws, as required by the independent claims. The Haas Article also discloses various other claimed features, including only having threaded bone screw holes in the plate head and using threaded bone screw holes on the plate shaft.

Detailed grounds for rejection are provided in the attached claim chart.

(ii) Claims 2, 3, and 5 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the Zimmer Ad in view of Haas and in further view of the Admitted Prior Art in the '486 Patent

As set forth in the chart, one of ordinary skill in the art would be further motivated to modify the combination in view of the Admitted Prior Art of the '486 patent. Indeed, one of ordinary skill in the art was well-aware of different types of screws, including self-tapping screws and self-drilling screws. These types of screws are nothing more than one of numerous existing screw types one of ordinary skill would find obvious for the intended use given the known advantages of using such screws.

Further, one of ordinary skill in the art was well-aware of screw holes that were longitudinally elongated and had an inclined edge given the known advantages of using such holes.

Detailed grounds for rejection are provided in the attached claim chart.

(iii) Claim 4 is rejected under 35 U.S.C. § 103(a) as rendered obvious by the Zimmer Ad in view of Haas and in further view of Decoste

As set forth in the chart, one of ordinary skill in the art would be further motivated to modify the combination in view of the cannulated screws disclosed in Decoste. Like the Zimmer Ad and the Haas Article, Decoste discloses devices for use in orthopedic bone surgery. One of ordinary skill in the art using guide wires to aid in accurate screw placement would be motivated to look to cannulated screws based on the advantages of doing of such screws.

Detailed grounds for rejection are provided in the attached claim chart.

(iv) Claims 8 and 18 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the Zimmer Ad in view of Haas and in further view of Klaue '544

As set forth in the chart, one of ordinary skill in the art would be further motivated to modify the combination in view of the trapezoidal shaped cross section disclosed in Klaue '544. Like the Zimmer Ad and the Haas Article, Klaue '544 discloses a bone plate. One of ordinary skill in the art seeking to reduce contact between the bone plate and the bone would refer to straight bone plates having limited contact features, such as Klaue '544's trapezoidal shaped cross section. Klaue '544 discloses that such a structure "minim[izes] bone contact, which in turn promotes vascularization and bone growth." Klaue '544, Col. 3, lines 46-48. Accordingly, it would have been obvious to one of ordinary skill in the art to modify the combination of the Zimmer Ad and the Haas Article to achieve the known and predictable benefits of promoting vascularization and bone growth.

Detailed grounds for rejection are provided in the attached claim chart.

(v) Claim 16 is rejected under 35 U.S.C. § 103(a) as rendered obvious by the Zimmer Ad in view of Haas and in further view of the Synthes Catalog

As set forth in the chart, one of ordinary skill in the art would be further motivated to modify the combination in view of the forked head disclosed in the Synthes Catalog. One of ordinary skill in the art seeking to improve the fit between the bone plate and bone would refer to shaped bone plates, such as that disclosed in the Synthes Catalog, and would be motivated to further modify the plate to have a head portion that flares out. Accordingly, it would have been obvious to one of ordinary skill in the art to modify the combination of the Zimmer Ad and the Haas Article to achieve the known and predictable benefits of providing a better fit to the bone.

Detailed grounds for rejection are provided in the attached claim chart.

22. The Zimmer Ad In View Of Gotfried

The attached Zimmer Ad in view of Gotfried § 103 Claim Chart (Exhibit DD) is incorporated by reference herein.

(i) Claims 1, 9, 14, 15, and 17 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the Zimmer Ad in view of Gotfried

As set forth in the chart, one of ordinary skill in the art would be further motivated to combine the Zimmer Ad with Gotfried. As the Examiner acknowledged during original prosecution, Gotfried discloses a bone plate having both unthreaded holes and threaded holes. *See* Second Office Action dated December 24, 2002, issued during the prosecution of the 09/660,287 application, at 2. Gotfried provides a clear motivation to use both threaded and non-threaded holes in the same plate, and also provides a motivation to use locking screws having a threaded head in such threaded holes. Furthermore, in Gotfried, the metaphysis portion of the bone is secured *solely* by threaded locking screws, which provides a motivation to use *only* locking screws through the bone plate head to secure the bone metaphysis. In view of these teachings, it would have been obvious to modify the Zimmer As plate to include a combination of unthreaded holes and threaded locking holes, to use locking screws with threaded heads (as recited in all of the '486 patent system claims), and to use only threaded locking holes through the bone plate head (as recited in claim 1). Thus, this obvious combination renders a number of the '486 patent system claims invalid, as explained in greater detail below and in the attached claim charts.

(ii) Claims 2, 3, and 5 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the Zimmer Ad in view of Gotfried and in further view of the Admitted Prior Art in the '486 Patent

As described above, one of ordinary skill in the art would be motivated to further modify this combination in view of the Admitted Prior Art in the '486 patent.

Detailed grounds for rejection are provided in the attached claim chart.

(iii) Claim 4 is rejected under 35 U.S.C. § 103(a) as rendered obvious by the Zimmer Ad in view of Gotfried and in further view of Decoste

As described above, one of ordinary skill in the art would be motivated to further modify this combination in view of the cannulated screws disclosed in Decoste.

Detailed grounds for rejection are provided in the attached claim chart.

(iv) Claims 6 and 7 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the Zimmer Ad in view of Gotfried and in further view of Haas

As described above, one of ordinary skill in the art would be motivated to further modify this combination in view of the threaded plate holes disclosed in Haas

Detailed grounds for rejection are provided in the attached claim chart.

(v) Claims 8 and 18 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the Zimmer Ad in view of Gotfried and in further view of Klaue '544

As described above, one of ordinary skill in the art would be motivated to further modify this combination in view of the trapeziodal shaped cross section disclosed in Klaue '544.

Detailed grounds for rejection are provided in the attached claim chart.

(vi) Claim 16 is rejected under 35 U.S.C. § 103(a) as rendered obvious by the Zimmer Ad in view of Gotfried and in further view of the Synthes Catalog

As described above, one of ordinary skill in the art would be motivated to further modify this combination in view of the forked head disclosed in the Synthes Catalog.

Detailed grounds for rejection are provided in the attached claim chart.

23. <u>The Zimmer Ad In View Of Wolter 117</u>

The attached Zimmer Ad in view of Wolter 117§ 103 Claim Chart (Exhibit EE) is incorporated by reference herein.

(i) Claims 1, 6, 7, 9, 14, 15, and 17 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the Zimmer Ad in view of Wolter 117

As set forth in the chart, one of ordinary skill in the art would be motivated to combine the Zimmer Ad's shaped bone plate with the conically-tapered and threaded holes and screws having heads with threads disclosed in Wolter 117. Wolter 117 discloses a bone plate having conically tapered, threaded holes having multiple lead threads, and corresponding locking screws having heads with threads. One seeking to improve the construction of the locking screw/plate interface refer to other bone plates having threaded holes and locking screws, and would be motivated to implement their known features.

Detailed grounds for rejection are provided in the attached claim chart.

(ii) Claims 2, 3, and 5 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the Schuhli Guide in view of Wolter 117 and in further view of the Admitted Prior Art in the '486 Patent

As described above, one of ordinary skill in the art would be motivated to further modify this combination in view of the Admitted Prior Art in the '486 patent.

Detailed grounds for rejection are provided in the attached claim chart.

(iii) Claim 4 is rejected under 35 U.S.C. § 103(a) as rendered obvious by the Zimmer Ad in view of Wolter 117 and in further view of Decoste

As described above, one of ordinary skill in the art would be motivated to further modify this combination in view of the cannulated screws disclosed in Decoste.

Detailed grounds for rejection are provided in the attached claim chart.

(iv) Claims 8 and 18 are rejected under 35 U.S.C. § 103(a) as rendered obvious by the Zimmer Ad in view of Wolter 117 and in further view of Klaue '544

As described above, one of ordinary skill in the art would be motivated to further modify this combination in view of the trapeziodal shaped cross section disclosed in Klaue '544.

Detailed grounds for rejection are provided in the attached claim chart.

(v) Claim 16 is rejected under 35 U.S.C. § 103(a) as rendered obvious by the Zimmer Ad in view of Wolter 117 and in further view of the Synthes Catalog

As described above, one of ordinary skill in the art would be motivated to further modify this combination in view of the forked head disclosed in the Synthes Catalog.

Detailed grounds for rejection are provided in the attached claim chart.

V. CONCLUSION

For the reasons set forth above, Requesters respectfully request reexamination and rejection of claims 1-18 of the '486 Patent.

Respectfully submitted,

Dated: 5/8/09

By: _____

Robert A. King
Registration No. 42,736

Hunton & Williams LLP
Intellectual Property Department
1900 K Street, N.W., Suite 1200
Washington, D.C. 20006-1109
(202) 955-1500 (telephone)
(202) 778-2201 (facsimile)

Attorney for Requester
Smith & Nephew, Inc.